Supreme Court, U.S.
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IN THE

# Supreme Court of the United States

MARY DOE, a human embryo "born" in the United States (and subsequently frozen in which state of cyro-preservation her life is presently suspended), individually and on behalf of all other frozen human embryos similarly situated, and the National Association for the Advancement of Preborn Children,

*Petitioners,*

*v.*

TOMMY G. THOMPSON, in his official capacity as Secretary of Health and Human Services; DEPARTMENT OF HEALTH AND HUMAN SERVICES; DR. HAROLD VARMUS, in his official capacity as Director of the National Institutes of Health; and NATIONAL INSTITUTES OF HEALTH,

*Respondents.*

On Petition For A Writ Of Certiorari
To The United States Court Of
Appeals For The Fourth Circuit

## PETITION FOR A WRIT OF CERTIORARI

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## QUESTIONS PRESENTED FOR REVIEW

1. Did the District Court err in dismissing on mootness grounds this action to enjoin, as unconstitutional, federal funding of human embryo/stem cell research, where the current Bush Administration policy already allows federal funding of stem cell research on a limited number of lines of stem cells extracted from human embryos prior to a specified date and time, and where it is not absolutely clear that the Federal Government will not revive the Clinton Administration policy of funding human embryo/stem cell research necessitating the extraction of additional lines of stem cells from human embryos–and their consequent destruction–in the future ?

2. Does Petitioner Mary Doe, a human embryo in vitro, have standing to sue?

## LIST OF PARTIES

Plaintiff Mary Doe is a human embryo "born" (produced or brought into life) in the United States, as that term is defined in the Fourteenth Amendment to the United States Constitution (and specifically as the word "born" is defined in Webster's Dictionary. Complete and Unabridged, of 1857, contemporaneous with the passage of the Fourteenth Amendment (1868)).

Plaintiff National Association for the Advancement of Preborn Children is an organization dedicated to the advocacy for the equal humanity and personhood of preborn children, including "children in vitro," with offices located in Hagerstown, Maryland.

Defendant Tommy G. Thompson, Secretary of Health and Human Services, head of the Department of Health and Human Services.

Defendant Department of Health and Human Services is an agency within the Executive Branch of the federal government.

Defendant Dr. Harold Varmus is currently the Director of National Institutes of Health, who has his office in Bethesda, Maryland.

Defendant National Institutes of Health is a division within the Department of Health and Human Services, with offices located in Bethesda, Maryland.

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## OPINIONS BELOW

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## JURISDICTION

The judgment of the Fourth Circuit was entered on December 7, 2004 (A-14). The Fourth Circuit denied Petitioner's timely Petition for Rehearing Or Rehearing En Banc on January 4, 2005(A-16). Jurisdiction of this Court to review the judgment of the Fourth Circuit is invoked pursuant to 28 U.S.C. § 1254(1).

## CONSTITUTIONAL PROVISIONS INVOLVED

Article III, Section 2 of the United States Constitution provides that The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority; –to all Cases Affecting Ambassadors, other public Ministers and Consuls;–to all Cases of admiralty and maritime Jurisdiction; –to Controversies to which the United States shall be a Party;–to Controversies between two or more States;–between a State and Citizens of another State;–between Citizens of different States;–between Citizens of the same State claiming Lands under Grants of different States, and between a State, or Citizens thereof, and foreign States, Citizens or Subjects.

## STATEMENT OF THE CASE

Plaintiff-Appellant Mary Doe is human embryo "born", i.e., produced or brought into life, in the United States, by in vitro fertilization (A-16). Her life was thereafter suspended by the freezing of the embryo in liquid nitrogen, a process known as cryo-preservation (A-16). The modern science of in vitro fertilization allows Mary Doe to be unfrozen and thereby returned to the warmth of life, after storage for months or years in a frozen state, and then to be implanted in the womb of an adopting mother as a "child in vitro" (A-38).

Prior to the Clinton Administration, all presidential administrations that had addressed the issue had banned human embryo experimentation (A-45). In response to attempts by the Clinton Administration to begin human embryo experimentation, the United States Congress, as part of certain stop-gap spending bills, added the proviso that no federal funds were to be used for human embryo experimentation (A-45).

In November 1998, President Clinton charged the National Bioethics Advisory Commission ("NBAC"), a Presidential Advisory Commission appointed under the Federal Advisory Committee Act (FACA), 5 U.S.C. , App. 2, § 1 et seq., with reviewing the issues associated with human stem cell[1] research, including balancing all ethical and medical issues (A-59). On July 13-14, 1999, NBAC issued a Draft Report, which concluded that federally funded scientists should be allowed to use "donated" human embryos for bio-medical research (A-61). The final NBAC report, which was issued in September 1999, recommended that federal funding should be made available for the use and extraction of stem cells from both cadaveric fetal tissue and "donated" embryos remaining after infertility treatments, and further recommended that the relevant

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[1]Embryonic stem cells are found in early-stage, animal embryos. Human stem cells can be extracted from, among other sources, human fetal tissue following an elective abortion and from "excess" human embryos that are created by in vitro fertilization for couples being treated for infertility. (See A-20, A-32 to A-33.)

statutes and regulations be amended to permit federal funding of such research (A-60).

The Department of Health and Human Services (DHHS) took the position that "stem cell research" did not fall within the Congressional ban against the use of federal funds for human embryo experimentation (A-45 to A-46). Specifically, DHHS was prohibited by appropriations law from using any appropriated funds "for the creation of a human embryo or embryos for research purposes; or research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 C.F.R. § 46.208(a)(2) [the DHHS human subject protection regulations] and section 498(b) of the Public Health Service Act (42 U.S.C. § 289f(b)" (A-61, quoting Public Law 106-113, § 510)). DHHS nevertheless concluded that, because stem cells are not embryos, this provision did not prohibit the use of federal funds for research using human stem cells that had been extracted from embryos–thereby destroying the embryos–using non-federal funding (A-62).

On or about August 10, 1999, Petitioner Mary Doe commenced this declaratory judgment action by filing her Complaint in the United States District Court for the District of Maryland (A-22, A-35). The Complaint premised jurisdiction on 28 U.S.C. § 1331, and named, as party defendants, Respondents Secretary of Health and Human Services, the Department of Health and Human Services, the Director of the National Institutes of Health, and the National Institutes of Health (A-35).

The Complaint sought a declaratory judgment that (1) the plaintiff Mary Doe, a human embryo, is a "person" entitled to the protection of the due process and equal protection clauses of the Fourteenth Amendment, (2) the recommendations of the National Bioethics Advisory Commission fail to recognize Mary Doe's "equal humanity and personhood and therefore, violate her rights to equal protection and the due process of law," and (3) that human embryo experimentation

that "results in the certain and sudden death of Mary Doe" violates her Fourteenth Amendment rights to equal protection and due process of law. The Complaint further sought the issuance of an injunction against the Defendants, "ordering them to cease and desist any and all plans to undertake human embryo (stem cell) experimentation" (A-50).

On December 2, 1999, the National Institutes of Health ("NIH") issued draft Guidelines for Research Involving Human Pluripotent Stem Cells. *See* DHHS, "Draft National Institutes of Health Guidelines for Research Involving Human Pluripotent Stem Cells", 64 Fed. Reg. 67576 (Dec. 2, 1999). The Draft NIH Guidelines applied to applications for NIH funding of research involving utilization of embryonic stem cells extracted from human embryos without DHHS funding, as well as to applications for NIH funding of research involving the derivation and/or utilization of embryonic stem cells from fetal tissue. *Id.* at 67577. Research to be funded by NIH under the guidelines was to involve stem cells extracted from either fetal tissue or from "donated" human embryos created by in vitro fertilization "in excess of clinical need", that had not been not implanted in a woman's uterus, and had not reached the stage when the first major tissue type is formed. *Id.* at 67577-78.

On or about January 5, 2000, Respondents moved to dismiss Mary Doe's Complaint, or, in the alternative, for summary judgment (A-24, A-51).

When the Bush administration came into office in early 2001, it announced its intention to review the Government's stem cell research policy. On August 9, 2001, President George W. Bush announced that federal funds may be awarded for research using human embryonic stem cells if the following criteria are met:

> [1] The derivative [i.e., the extraction] process (which begins with the destruction of the embryo) was initiated prior to 9:00 p.m. EDT on August 9, 2001.
>
> [2] The stem cells must have been derived from an embryo that was created for reproductive purposes and

was no longer needed.

[3] Informed consent must have been obtained for the donation of the embryo and that donation must not have involved financial inducements. (A-87 to A-89.)

On or about October 25, 2002, Respondents moved to dismiss the case as moot (A-51).

In dismissing the case as moot, the District Court found that, "[f]rom all that appears, the National Institutes of Health (NIH), the real party-defendant in interest, has been in compliance with [the Bush Administration] policy" (A-11). The District Court, without making any determination as to the possibility or likelihood of a further change in the Government's policy regarding stem cell research, agreed with the Government's argument that "the current policy and the fact of NIH's compliance have mooted the original suit brought by Plaintiffs" and that therefore "closure of the case is appropriate" (A-11).

In affirming the District Court's dismissal, the Fourth Circuit determined that "the Government has carried its burden of demonstrating that it will not revive President Clinton's policy concerning embryonic stem-cell research" (A-7). The court further stated that "there is no evidence suggesting that the Government is likely to revive the policy that is the subject of this lawsuit" (A-8).

## REASONS WHY THE PETITION SHOULD BE GRANTED

### I. The Fourth Circuit's Decision Conflicts With This Court's *Adarand Constructors* Decision Placing A "Heavy Burden" On Government Officials To Demonstrate Mootness Is "Absolutely Clear".

This Petition raises a very important and unsettled question of federal law regarding mootness, specifically the application of the "voluntary cessation" doctrine to a change in

administrative policy instituted by the President of the United States himself. The Fourth Circuit, moreover, decided this question in a way that conflicts with relevant decisions of this Court.

Mootness is primarily a function of the Article III "case or controversy" limitation on the jurisdiction of the Federal courts. A case is moot when the issues presented are not longer "live" or the parties lack a legally cognizable interest in the outcome. *City of Erie v. Pap's A.M.*, 529 U.S. 277, 287 (2000). To survive an assertion that a claim is moot, a party must have suffered an actual injury that can be redressed by a favorable judicial decision. *Iron Arrow Honor Society v. Heckler,* 464 U.S. 67, 70 (1983).

Nevertheless, it is by now well established that "[v]oluntary cessation of challenged conduct moots a case . . . only if it is '*absolutely* clear that the allegedly wrongful behavior could not reasonably be expected to recur.'" *Adarand Constructors, Inc. v. Slater,* 528 U.S. 216, 222 (2000) (quoting *United States v. Concentrated Phosphate Export Ass'n, Inc.,* 393 U.S. 199, 203 (1968)) (emphasis the Court's). As this Court has noted, "[t]he plain lesson of [our precedents] is that there are circumstances in which the prospect that a defendant will engage in (or resume) harmful conduct may be too speculative to support standing, *but not too speculative to overcome mootness.*" *Friends of Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 190 (2000) (emphasis added). Moreover, "the 'heavy burden of persuading the court that the challenged conduct cannot reasonably be expected to start up again *lies with the party asserting mootness.*'" *Adarand Constructors, Inc. v. Slater,* 528 U.S. at 222 (quoting *Friends of Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.,* 528 U.S. at 189 (2000)) (emphasis the Court's).

These principles apply to governmental administrative policies, not just private conduct. In *Adarand Constructors, Inc. v. Slater,* the defendants, federal Department of Transportation (DOT) officials, claimed that a change in administrative policy had mooted the case. This Court disagreed, reasoning that the

DOT officials have failed to carry their "heavy burden" to show that it was "absolutely clear" that the challenged, prior administrative policy could not reasonably be expected to be applied in the future. 528 U.S. at 222. *Adarand Constructors* clarified that, like private parties, federal government *"[o]fficials* who claim that a changed course of behavior moots a challenge to their prior actions bear a 'heavy burden' of persuading the court that resumption cannot reasonably be expected." 13A Wright & Miller, *Federal Practice & Procedure,* § 3533.7 n. 2 (Supp. 2004) (emphasis added), citing *Adarand Constructors, Inc. v. Slater.*

The Fourth Circuit, however, did not, as this Court's precedents require, place a "heavy burden" on the Government to show that it was "absolutely clear" that federal funding of research involving the extraction of new stem-cell lines and the consequent destruction of human embryos could not reasonably be expected to recur. Rather, the Fourth Circuit determined that the Government had met its burden merely by showing that the Government is not *"likely to revive"* the prior policy authorizing such federal funding. Without discussing or even citing to *Adarand Constructors*, the appeals court erroneously concluded that this case was governed by Supreme Court and Fourth Circuit authority holding that challenges to statutes or ordinances that are later amended or repealed ordinarily generally become moot upon such amendment or repeal, unless there is a substantial likelihood that the legislature would enact a similar statute or ordinance if the lawsuit is dismissed. *See, e.g., Northeastern Fla. Chapter of the Associated Gen. Contractors of Am. v. City of Jacksonville,* 508 U.S. 656, 662 (1993); *American Legion Post 7 v. City of Durham,* 239 F.3d 601, 606 (4th Cir. 2001); *Valero Terrestial Corp. v. Paige,* 211 F.3d 112, 116 (4th Cir. 2000).

As the instant case involves a challenge to a federal administrative policy that was voluntarily discontinued, rather than to a statute or ordinance that was subsequently amended or repealed, resolution of the question of mootness is governed by the principles laid down by this Court in *Adarand*

*Constructors*. The Fourth Circuit therefore decided the important question of mootness raised by this petition in a way that conflicts directly with *Adarand Constructors*.

Indeed, this question of mootness is an exceptionally important one of first impression regarding application of the "voluntary cessation" principle to a voluntary change in administrative policy *that is instituted by the President of the United States*, rather than by a federal agency or by subordinate agency officials. For there to be a revival of the original, challenged policy, the President himself need only change his mind. It is respectfully submitted that this presents a far different situation from that posed by the cases relied upon by the Fourth Circuit involving the repeal or amendment of a challenged legislative enactment, where re-enactment of the same or a similar measure requires the concurrent vote of an often very large group of legislators.

Furthermore, the Fourth Circuit based its determination that the Government was not likely to revive the challenged administrative policy on the following: (1) the National Institutes of Health (NIH) "officially withdrew" its guidelines implementing the former, Clinton administration policy; (2) NIH "is following [the current Bush administration] policy" allowing federal funds to be used "only for research involving *existing* embryonic stem-cell line"; and (3) "no federal funds are being used" to further research involving embryonic stem-cell lines "that have not yet been generated from extant embryos" (A-2 (emphasis in original).)

The lower court thereby focused solely on evidence in the record regarding the past or current actions of the Government ("withdrew," "is following," "no federal funds are being used"). It thereby overlooked the evidence of record strongly indicating that there is at least a reasonable expectation that the Government may change its mind and resume the challenged Clinton administration policies in the future.

First, the Fourth Circuit entirely ignored the total absence in the record of any demonstration, representation,

contention, assertion, or promise by either the Government, or by the various federal government officials and agencies named as defendants in this case, that they will never again institute a policy to require, approve or otherwise allow federal funding of embryonic stem-cell research necessitating the destruction of additional human embryos. *See Norman-Bloodsaw v. Lawrence Berkeley Laboratory,* 135 F.3d 1260 (9th Cir. 1998), wherein the Ninth Circuit rejected the argument of the Secretary of Department of Energy that claims against him for injunctive and declaratory relief were moot because the DOE order requiring the challenged syphilis testing had been cancelled and replaced by a different order, pointing out that the Defendants "do not contend that the Department will never again require or permit, or that Lawrence will never again conduct, the tests at issue." 135 F.3d at 1274. Secondly, the Fourth Circuit also overlooked the evidence of record that, by the Government's own admission, there are, at most, only a very limited number (approximately 60 to 80) of "existing" stem-cell lines that can now be used in federally funded stem-cell research. (A-88, Brief for Appellees at page 8). The Government neither has promised to terminate federally funded stem-cell research upon the exhaustion of these existing lines, nor offered any reason or explanation as to why, upon the inevitable exhaustion of these "existing" stem-cell lines, continued federally-funded research would not require the destruction of additional human embryos. *Cf. Norman-Bloodsaw v. Lawrence Berkeley Laboratory,* 135 F.3d at 1274, rejecting Government's mootness argument where "[d]efendants have neither asserted nor demonstrated that they will never resume mandatory testing for intimate medical conditions; nor have they offered any reason why they might not return in the future to their original views on the utility of mandatory testing."

Finally, the appeals court also did not acknowledge the facts that (1) President Clinton did not institute the challenged policy to permit federal funding of stem-cell research on human embryos until November 1998, well into the second term of his

presidency (A-3); that (2) Senator John Kerry, during his failed, 2004 bid for the presidency as the Democrat Party's presidential nominee, repeatedly promised to revive the challenged, Clinton Administration policy regarding federal funding of human embryo, stem-cell research; and that (3), when President Bush's term of office expires in January 2009, the next administration, whether Republican or Democrat, will be free to institute an entirely different policy regarding federal funding of human embryo, stem-cell research.

By failing to take into consideration the facts of record bearing on the reasonable possibility or likelihood that the Government will resume the challenged conduct in the future, the court below erroneously failed to determine that, "under the circumstances of this case, it is impossible to conclude that [the Government] ha[s] borne [its] burden of establishing that it is 'absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur.'" *Adarand Constructors, Inc. v. Slater,* 528 U.S. at 224 (quoting *Friends of Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.,* 528 U.S. at 189.)

The Court should therefore grant the Petition to resolve the conflict between the Fourth Circuit's decision and this Court's holding in *Adarand Constructors* and to decide the very important question of mootness involving the application of the "voluntary cessation" doctrine to policies that are instituted and withdrawn by the President.

## II. MARY DOE, A HUMAN EMBRYO, HAS STANDING TO SUE TO PREVENT HER DESTRUCTION.

Because this case is clearly not moot, this appeal also presents a fundamentally and exceptionally important issue regarding the standing of a human embryo *in vitro* to protect herself and other similarly situated human embryos from destruction at the hands of federally funded researchers. Mary Doe is neither "experimental material that [one can] throw

away after using it," nor a "commodit[y]," nor "property." Rather, she is an "early human being" who should be accorded standing to defend herself against the threat of her imminent destruction in experimental research. Because this case is not moot, this Court should address this fundamental issue as well.

"'The being that is now you or me is the same being that was once an adolescent, and before that a toddler, and before that an infant, and before that a fetus, *and before that an embryo. To have destroyed the being that is you or me at any of these stages would have been to destroy you or me.*'" Sameul B. Casey & Nathan A. Adams, "Specially Respecting The Living Human Embryo By Adhering To Standard Human Subject Experimentation Rules," 2 *Yale J. Health Policy, Law & Ethics* 111 (2001) (quoting Robert George, "Stem Cell Research: A Debate; Don't Destroy Human Life," *Wall Street Journal,* July 30, 2001) (emphasis added). Mary Doe, a developing human life, should be accorded standing in order to assert her right to be free from destruction at the hands of medical researchers.

In the only prior federal decision to address this issue, *Doe v. Shalala*, 862 F. Supp. 1421 (D. Md. 1994), the plaintiffs, including Mary Doe, a human embryo, filed a class action suit on behalf of more than 20,000 embryos stored in various IVF labs across the United States. Plaintiffs asserted that the National Institutes of Health Human Embryo Research Panel ("the Panel") was not "fairly balanced" within the meaning of the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2 § 5(b)(2). They alleged that at least ten (10) members of the Panel were "current or former NIH grantees who [had] firmly endorsed the principle and many of the protocols of extended and unfettered human embryo research." 862 F. Supp. at 1426. Arguing that the Panel's bias and likely favorable recommendations on the funding of embryo research would cause them irreparable harm, the plaintiffs sought a preliminary injunction to halt further Panel deliberation and publication of a Report. *Id.*

The District Court dismissed the suit for lack of standing, saying:

> [P]hilosophical and religious considerations aside, the Supreme Court has made it clear that the word "person," as used in the Fourteenth Amendment, does not include the unborn. *Roe v. Wade*, 410 U.S. 113, 158 . . . (1973). It has thus been held that embryos are not persons with legally protectable interests within the meaning of Fed.R.Civ.P. 17(c) such that appointments of *guardians ad litem* are warranted or required. *See Roe v. Casey,* 464 F. Supp. 483 (E.D. Pa. 1978), aff'd, 623 F.2d 829 (3d Cir. 1980). The Court sees no distinction between fetuses *in utero* or *ex utero*.

*Id.*

The District Court in *Doe v. Shalala* "did not consider whether the embryos [ex utero, including Mary Doe,] deserved different treatment–or legal opportunities–as the subjects of scientific research" than a unborn child in a mother's womb, as it "believed such questions had already been answered by *Roe [v. Wade*, 410 U.S. 113 (1973)] and [*Roe v.*] *Casey* [, 464 F. Supp. 483 (E.D. Pa. 1978), *aff'd*, 623 F.2d 829 (3d Cir. 1980).]" Christine L. Feiler, "Human Embryo Experimentation: Regulation and Relative Rights," 66 *Fordham L. Rev.* 2435, 2445 (1998). *Roe* and *Casey*, however, were abortion cases, involving the fetus or embryo *in utero*, and the holdings in those cases were greatly influenced by the competing interests and constitutional rights of the mother:

> The abortion cases were decided in a normative adversarial context: The woman's right to control her own body was pitted against the fetus's proposed right to be born. *Roe* and its successors make clear that a woman's liberty interests in reproductive autonomy and bodily integrity often outweigh the State's interest in protecting unborn life.

Feiler, 66 *Fordham L. Rev.* at 2445-46 (footnotes omitted).

By contrast, "the discussion of the embryo's status [as the subject of scientific research or experimentation] must necessarily stand on a different legal footing than that of the discussion of fetal abortion." Dan L. Burk, "Patenting Transgenic Human Embryos: A Nonuse Cost Perspective," 30 *Hous. L. Rev.* 1597, 1652 (1993). "[E]ven strong pro-abortion proponents acknowledge that *Roe v. Wade* has no necessary bearing upon the ex utero living human embryo where maternal and fetal rights are not in opposition." Casey & Adams, 2 *Yale J. Health Policy, Law & Ethics* at 118-19.

The standing issue presented by this case, like that presented in *Doe v. Shalala*, is therefore "fundamentally different from . . .[that presented in the cases involving] abortion [such as *Roe* and *Casey*] . . . because individual reproductive autonomy is not implicated." Feiler, *Fordham L. Rev.* at 2446. As one of the most notable proponents of the right to abortion has admitted, "[b]ut for its biological dependence on the woman, it is at least arguable that the fetus could be regarded as a holder of rights under the due process clause of the fifth and fourteenth amendments, as well as the equal protection clause of the latter." Laurence H. Tribe, "The Abortion Funding Conundrum: Inalienable Rights, Affirmative Duties, and the Dilemma of Dependence," 99 *Harv. L. Rev.* 330, 340 (1985). The human embryo *ex utero* enjoys such independence, *see* Feiler, 66 *Fordham L. Rev.* at 2446 ("The research embryo is an independent entity whose existence does not require a woman to sacrifice her constitutionally protected autonomy."); Burk, 30 *Hous. L. Rev.* at 1653 ("[U]nlike a fetus, the embryo can exist independently outside the womb; . . . [c]onsequently, the autonomy of the mother need not enter into the discussion of embryo status at all[.]"), and should therefore be accorded both standing and protection as a "person" under the due process and equal protection clauses of the Fourteenth Amendment.

Standing should also be accorded Mary Doe for the following compelling reasons. First, the embryo "is an instance of human life", Feiler, 66 *Fordham L. Rev.* at 2450, i.e., as it is

both "living and genetically unique" and "human and capable of developing into an adult." Casey & Adams, 2 *Yale J. Health Policy, Law & Ethics* at 111. In short, "embryos are developing human lives." Feiler, 66 *Fordham L. Rev.* at 2453. Second, "[e]mbryos are the most immature and utterly incapacitated human entities," Feiler, 66 *Fordham L. Rev.* at 2452, and they "are incapable of giving consent to their . . . use in experimental procedures." Id. Finally, "derivation of human stem cells from embryos terminates them." Casey & Adams, 2 *Yale J. Health Policy, Law & Ethics* at 111. Researchers must inevitably destroy embryos in order to gain the knowledge that they want. Feiler, 66 *Fordham L. Rev.* at 2453.

Thus, human embryos, such as Mary Doe, deserve and need extensive protection from "the inevitable risk and ultimate harm of manipulation and destruction at the hands of researchers." Feiler, 66 *Fordham L. Rev.* at 2452. Absent the conferral of standing to seek judicial relief, Mary Doe and the other embryos she seeks to represent will have no assurance such protection will ever be extended. Furthermore, if such standing is denied, "the utilitarian fog into which medical researchers [performing human embryo stem cell research] will travel in the years to come will surely take American medical researchers down the darkened and dead-ended roads previously traveled from Buchenwald to Tuskegee." *Cf.* Casey & Adams, 2 *Yale J. Health Policy, Law & Ethics* at 112 (footnotes omitted).

For all of the above reasons, Mary Doe submits that she and her fellow human embryos *ex utero* should be accorded standing to pursue the instant litigation.

## CONCLUSION

In view of the reasons and authorities set forth above, Petitioner Mary Doe urges this Court to prevent her future destruction by issuing a Writ of Certiorari to the Fourth Circuit Court of Appeals, reversing the Fourth Circuit's judgment affirming the District Court's dismissal of this case as moot, and remanding this matter for further proceedings.

Respectfully submitted,


_____/s/_____

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Westlaw
112 Fed.Appx 600
112 Fed.Appx. 600, 2004 WL 2800941 (4th Cir.(Md..))
(Cite as: 122 Fed.Appx. 600, 2004 WL 2800941 (4th Cir.(Md.)))

**H**

**Briefs and other Related Documents**

This case was not selected for publication in the Federal Reporter.

UNPUBLISHED

Please use FIND to look at the applicable circuit court rule before citing this opinion. Fourth Circuit Rule 36 (c). (FIND CTA 4 Rule 36(c).)

United States Court of Appeals,
Fourth Circuit.
Mary Doe, a human embryo "born" in the United States (and subsequently frozen in which state of cryopreservation her life is presently suspended), individually and on behalf of all other frozen human embryos similarly situated, Plaintiff-Appellant,
v.
Donna E. SHALALA, Secretary, United States Department of Health and Human Services, in her official capacity as Secretary of Health and Human Services; Department of Health and Human Services, Social Security; Harold Varmus, Doctor, in his official capacity as Director of the National Institutes of Health, Defendants—Appellees.
**No. 03-2254.**

Argued Oct. 27, 2004
Decided Dec. 7, 2004.

**Background:** Advocacy group filed suit on behalf of frozen human embryos seeking declaration that embryos were entitle to protection under federal constitution and permanent injunction against embryonic stem cell experimentation. The United States District Court for the District of Maryland, Peter J. Messitte. J, dismissed complaint, and group appealed.

**Holding:** The Court Appeals held that action was renderd most by subsequent adoption of newdederal policy.
Affirmed.

West Headnotes
**Federal Courts 13**
170Bk13 Most Cited Cases
Action brought on behalf of frozen human embryos challenging federal government's policy concerning embryonic stem cell research was rendered moot by subsequent adoption of new policy limiting federal funding of embryonic stem-cell research to projects involving existing stem-cell lines, where embryos were not threatened by new policy. National Institutes of Health (NH) officially withdrew its guidelines implementing former policy, no federal funds were being used to further research involving embryonic stem-cell lines that had not yet been generated from extant embryos, and there was no reasonable expectation that embryos would be subject to former policy on stem cell research again.
U.S.C.A. Const. Art 3 ß 2, cl.1.
***600** Appeal from the United States District Court fro the District of Maryland at Greenbelt. Peter J. Messitte, District Judge. (CA-99-2428-PJM).

**ARGUED:** Rudolph Martin Palmer Jr., Hagerstown, Maryland, for Appellant. Thomas Mark Bondy, Civil Rights Division, Appellate Section, United States Department of Justice, Washington, DC, for Appellees. **ON BRIEF:** Peter D. Keisler, Assistant Attorney General, Thomas M. DiBiagio, United States Arrorney, Mark B. Stern, Appellate Staff, Civil

Division, United States Department of Justice, Washignton, DC, for Appelless.

Before LUTTIG, KING, and SHEDD, Circuit Judges.

Affirmed by unpublished PER CURIAM opinion.

Unpublished opinions are not binding precedent in this circuit. See Local Rule 36(c).

*601 PER CURIAM

**1 Mary Doe is the name given to an embryo produced by means of *in vitro* fertilization and now cryogenically preserved in liquid nitrogen. In August 1999, the National Association for the Advancement of Preborn Children ("NAAPC") FILED SUIT ON Mary Doe's behalf, seeking a declaration that Mary Doe is entitle to due process of law and the equal protection of laws under the Fourteenth Amendment and permanent injunction against "any and all plans to undertake human embryo (stem cell) experimentation." This lawsuit came in response to what NAAPC perceived as President Clinton's policy favoring embryonic stem cell research. In August 2001, President Bush announced a new policy limiting federal funding for embryonic stem-cell research to projects involving already-existing stem-cell lines. Because Mary Doe would not be threatened by this policy, the Government moved the district court to dismiss this case as moot. The district court granted the motion, and we affirm.

1.
In November 1998, then-President Clinton directed the National Bioethics Advisory Commission ("NABAC" ) to review federal policy concerning human stem-cell research. The final report of the NABAC, issued in September 1999, recommended that federal statutes and regulations be amended to permit funding for the use and derivation of embryonic stem cells from

cadaveric fetal tissue and embryos remaining after infertility treatments. Later that year, the National Institutes of Health ("NIH") published draft guidelines regarding stem-cell research funding. 64 Fed. Reg. 67.576 (Dec. 2, 1999). Under these guidelines, any future research funded by NIH would involve stem cells derived from fetal tissue or from certain early embryos that are the products of *in vitro* fertilization. *Id.* at 67.577. NIH issued its final guidelines in August 2000. 65 Fed. Reg. 51.976 (Aug. 25, 2000).

Mary Doe and the NAAPC (collectively, "Plaintiffs") commenced this lawsuit to challenge President Clinton's policy. Plaintiff's complaint alleged that the Government could not implement that policy without violating Mary Doe's constitutional rights, especially her rights under the Fourteenth Amendment. Plaintiff's requested that the district court "declare the equal humanity and personhood of Mary Doe and grant her equal protection and due process of the laws," find President Clinton's policy unconstitutional, and enjoin the Government to "cease and desist any and all plans to undertake human embryo (stem cell) experimentation."

In August 2001—while this lawsuit was pending—President Bush announced a new policy concerning federal funding for stem-cell research. Under President Bush's policy, federal funding would remain available for research involving *existing* stem cell lines, with the following conditions: (1) the stem cells must have been derived from an embryo that was created for reproductive purposes, (2) the embryo was no longer needed for those purpose, (3) informed consent must have been obtained for donation of the embryo, and (4) no financial inducements were provided for donation for the embryo. Federal funding would not be available for stem-cell research involving embyos that had not yet been destroyed. In response to this new policy, NIH announced in November 2001 that it was withdrawing its earlier-issued guidelines. See 66 Fed. Rd. 57.107(Nov. 14, 2001).

**2 Arguing that the current policy poses no threat to Mary Doe, the Government moved the district court to dismiss Plaintiffs' challenge to the former policy as *602 moot. The district court dismissed the case, and this appeal followed.

II.

The district court's ruling on mootness presents a question of law that we review *de novo*. *See* Troiano v. Supervisor of Elections, 382 F. 3d 255, 262 (4th Cir.2001) (applying the same standard of review to a ruling on standing).

> "Under Article III of the Constitution, federal courts may adjudicate only actual, ongoing cases or controversies. To invoke the jurisdiction of a federal court may adjudicate only actual, ongoing cases or controversies. To invoke the jurisdiction of a federal court, a litigant must have suffered, or be threatened with, an actual injury traceable to the defendant and likely to be redressed by a favorable judicial decision."

Lewis v. Continental Bank Corp., 494 U.S. 472, 477, 110 S.Ct. 1249, 108 L. Ed.2d 400 (1990). This requirement ensures that federal courts will resolve only "real and substantial controversies admitting of specific relief through a decree of a conclusive character" and will not issue opinions "advising what the law would be upon a hypothetical state of facts." *Id.* (internal quotations omitted) Since the Government has changed its policy concerning embryonic stem-cell research, Mary Doe is not now threatened with any injury traceable to the defendants. Thus, any ruling on the merits of Mary Doe's Claims would be nothing other than an "advisory opinion[ ] on abstract propositions of the law." Hall v. Beals, 396 U.S. 45, 48, 90 S.Ct. 200, 24 L.Ed.2d214(1969) (per curiam).

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A.

Plaintiffs argue that the mere voluntary cessation of illegal conduct does not moot their ongoing challenge to that conduct. Although "voluntary cessation of allegedly illegal conduct does not deprive the tribunal of power to hear and determine the case , i.e., does not make the case moot," *United States v. W.T. Grants Co.*, 345 U.S. 620, 632, 73 S.Ct. 894, 97 L.Ed. 1303 (1953), a case may nevertheless be moot "if subsequent events made it absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur," *Friends of the Earth, Inc. v. Laidlaw Env'l Servs.* (TOC), *Inc.*, 528 U.S. 167, 189, 120 S.Ct. 693, 145 L.Ed.2d 610 (2000). The party asserting mootness bears the burden to show that the challenged conduct cannot reasonably be expected to recur. *Id.*

A legislature may voluntarily cease allegedly illegal conduct by amending or repealing the challenged law or by allowing it to expire. In general, the amendment, repeal, or expiration of a statute moots any challenge to that statute. *See* *Lewis*, 494 U.S. at 474; *Valero Terrestrial Corp v. Paige*, 211 F.3d 112, 116 (4th Cir.2000). The Supreme Court has held such statutory challenges not moot only where it appeared likely that the legislature would enact a similar policy if the lawsuit were dismissed. *See* *Northeaster Fla. Chapter of the Associated Gen. Contractors of Am. v. City of Jacksonville, Fla.*, 508 U.S. 656, 662, 113 S.Ct 2297, 124 L.Ed2d 586(1993); *City of Mesquite v. Aladdin's Castle, Inc.*, *455 U.S. 283, 289 & n.* 11, 102 S.Ct. 1070, 71L.Ed.2d 152 (1982)

**3 We have noticed that the *City of Mesquite* line of cases is "generally limited to the circumstance, and like circumstances, in which a defendant openly announces its intention to reenact precisely the same provision held constitutional below." *Valero Terrestrial*, 211 F.3d at 116. Similarly, we stated in *American Legion Post 7 v. City of Durham*, 239 F.3d 601 (4th Cir.2001), that "[t]he practical likelihood of reenactment of the challenged law appears *603 to be the key to the Supreme Court's

mootness jurisprudence" in this context. *Id.* at 606. We concluded in *American Legion* that a city's amending a zoning ordinance alleged to violate the First Amendment mooted the plaintiff's challenge to the ordinance, because there was "little likelihood" that they city would revive the original ordiance. *Id.*

Plaintiffs contend that these authorities are inapposite because they involved statues or ordinances rather than administrative polices or regulations. According to Plaintiffs, the ease with which administrative actions can be changed makes it likely that the conduct they challenge will recur. We have noted, however, that "[w]ithdrawal or alteration of administrative policies can moot an attack on these policies," *Bahmiller v. Derwinski*, 923 F.2d 1085, 1089 (4th Cir.1991), suggesting that ordinary mootness principles apply to administrative as well as legislative action. In *Commonwealth of Virginia v. Califano*, 631 F.2d 324 (4th Cir.1980), for example, we applied ordinary mootness principles to a state's challenge to a decision by a federal agency concerning the state's welfare program. Although the federal agency agreed to give the sate the relief it sought-a formal hearing on the state's amendment of its welfare program—the agency refused to concede that the state was entitled to that relief as a matter of right and insisted that it would continue to act as it had in the past. *Id.* at 326. Under these circumstances, we concluded that the agency had failed to carry its burden of demostration that there was "no reasonable expectation that the wrong [would] be repeated, " and we held that the state's challenge was not moot. *Id.* at 326-27. It is of no consequence that the challenged conduct in this case is administrative rather than legislative in character.

In this case, the Government has carried its burden of demonstrating that it will not revive President Clinton's policy concerning embryonic stem-cell research. NIH officially withdrew its guidelines implementing the former policy. The current policy allows federal funds to be used only for research involving *existing* embryonic stem-cell lines, and NIH is

following that policy. No federal funds are being used to further research involving embryonic stem-cell lines that have not yet been generated from extant embryos such as Mary Doe. In short, there is no evidence suggesting that the Government is likely to revive the policy that is the subject of this lawsuit. *American Legion*, 239 F.3d at 606.

B.

**4 Plaintiffs further contend that this case is not moot because the challenged conduct is capable of repetition, yet evading review. "The capable of repetition doctrine applies only in exceptional situations, where the following two circumstances are simultaneously present: (1) the challenged action is in its duration too short to be fully litigated prior to cessation or expiration, and (2) there is a reasonable expectation that the same complaining party will be subject to the same action again." *Spencer v. Kenna*, 523 U.S. 1, 17, 118 S.Ct 978, 140 L.Ed2d 43 (1998) (internal citations and quotations omitted). For the reasons stated above, there is no reasonable expectation that Mary Doe will be subject to the former policy on stem-cell research again. The replacement of that policy with a new policy "diminishes the potential for repetition of the dispute that brought about this litigation." *Pressley Ridge Schs. V. Shimer*, 134 F.3d 1218, 1221, (4th Cir.1998) (noting that an agency's amending the challenged regulation made it less likely that the alleged injury would be repeated).

***604 C.**

Finally, Plaintiffs argue that Mary Doe and other similarly situated embryos retain an interest in the outcome of this litigation. Plaintiffs argue that by limiting federal funding to research involving only existing embryonic stem-cell lines, the Government has threatened to deplete the supply of embryonic stem cells. As a result, private researchers likely will make greater use of extant embryos such as Mary Doe. This argument is meritless. First, Plaintiffs can only speculate about the reaction of private-sector researchers to the current policy

on stem-cell research. Second, the challenge mounted in this lawsuit is to the Government's policy for federal funding, not the private sector's response to that policy. The fact remains that Mary Doe is not now threatened with any injury traceable to the defendants in the lawsuit. *See* Lewis, 494 U.s. at 477.

III.

Because the current policy limiting federal funding of embryonic stem-cell research to projects involving existing stem-cell lines poses no threat to Mary Doe, her challenge to the former policy is moot. Accordingly, the judgement of the district court is

*AFFRIMED*

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**Briefs and Ither Related Documents (Back to top)**

03-2254 (Docket)

(Oct. 20, 2003)

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122Fed.Appx 600, 2004 WL 2800941 (4th Cir.(Md.))
**(Cite as: 122 Fed.Appx. 600, 2004 WL 2800941 (4th Cir.(Md.)))**

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

| | | |
|---|---|---|
| MARY DOE, et al., | * | |
| | * | |
| Plaintiffs | * | |
| | * | |
| v. | * | Civil No. PJM 99-2428 |
| | * | |
| TOMMY G. THOMPSON,[1] | * | |
| Secretary of the Department of | * | |
| Health and Human Services, et al., | * | |
| Defendants | * | |

MEMORANDUM OPINION

This case has been administratively closed since February 26, 2001. Plaintiffs appealed to the Court's closure order to the U.S. Court of Appeals for the Fourth Circuit, which affirmed, and to the Supreme Court, which denied certiorari. Shortly after the Supreme Court's denial of certiorari, Plaintiffs returned to this Court and filed a Motion for Contempt [Paper No. 59]; Defendants filed a Motion to Deny Plaintiff's Motion for Contempt and [to] Close Case [Paper No. 60]; and Plaintiff's filed a Request to Re-Open the Case [Paper No. 61] and a Request for Oral Argument and Judgment on the Pleadings [Paper No. 63]. The Court will GRANT Defendants' Motion to Deny Plaintiff's Motion for Contempt and [to] Close Case. All other motions will be DENIED. The case will be CLOSED.

I.

In this litigation, Plaintiffs sought to block research involving human stem-cells on the grounds that the rights of

[1]At the time suite was filed, Donna Shalala, then Secretary of the Department of Health and Human Services, was a named Defendant. Tommy G. Thompson is the current Secretary of the Department.

human embryos were being violated by government-funded research. Suit commenced during the Clinton presidential administration, which appeared prepared to permit relatively broad-scale stem-cell research and experimentation. When the newly-elected Bush administration announced its intention to review the Government's stem-cell-research policy, the Court entered its administrative stay order. Given the possibility that the new administration might significantly modify the prior administration's policy, the Court anticipated that, other legal issues in the case aside, the core dispute might become moot. That has turned out to be the case.

On August 9, 2001, President Bush announced the current Government policy regarding stem-cell research, pursuant to which federal funding will only be distributed with respect to a limited number of existing stem-cell lines. From all that appears, the National Institutes of Health (NIH), the real party-defendant in interest, has been in compliance with that policy.[2] The Government argues that the current policy and the fact of NIH's compliance have mooted the original suit brought by Plaintiffs. The Court agrees with the Government and, therefore, holds that closure of the case is appropriate.

**II.**

A final word is appropriate with respect to Plaintiffs' Motion for Contempt. At the time the Court entered its order

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[2]The Stem Cell Information web-page of NIH currently states:

- On August 9th 2001, President George W. Bush announced that federal funds may be awarded for research using human embryonic stem cells if the following criteria are met:
    - The derivation process (which begins with the destruction of the embryo) was initiated prior to 9:00 p.m. EDT on August 9, 2001.
    - The stem cells must have been derived from an embryo that was created for reproductive purposes and was no longer needed.
    - Informed consent must have been obtained for the donation of the embryo and that donation must not have involved financial inducements.
- The NIH, as the Federal government's leading biomedical research organization, is implementing the President's policy. The NIH funds research scientists to conduct research on existing human embryonic stem cells and to explore the enormous promise of these unique cells, including their potential to produce breakthrough therapies and cures.

of administrative stay, it directed the Government to file reports at 60-day intervals advising the Court and Plaintiffs of possible changes in the Government's stem-cell research policy. Until October 29, 2001, the Government duly complied with this directive. Because the Government did not file any reports thereafter, Plaintiffs—approximately one year later—filed their Motion for Contempt. In opposition to the Motion, the Government argues that, with President Bush's speech of August 9, 2001, the reason for the Court's periodic reporting requirement also came to an end.

Although it would have been more prudent for the Government to solicit the Court's permission before ceasing its report, the court agrees that the ultimate objective of the reporting requirement was satisfied when President Bush proclaimed his Administration's policy regarding stem-cell research. In any event, there is no indication that the Government has in any way proceeding in bad faith in the matter. All things considered, therefore, the Court declines to hold the Government in contempt.

**III.**

A separate Order will issue implementing this decision.

July 3rd, 2003

/s/
PETER J. MESSITTE
UNITED STATES DISTRICT JUDGE

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Investigators from ten laboratories in the United Sates, Australia, India, Israel, and Sweden have derived stem cells from 71 individual, genetically diverse blastocysts. These derivations meet the President's criteria for use in federally funded human embryonic stem cell research. The NIH has consulted with each of the investigators who have derived these cells. These scientists are working with the NIH and the research community to establish a research infrastructure to ensure the successful handling and use of these cells in the laboratory.

National Institutes of Health, Stem Cell Information, NIH's Role in Federal Policy, available at http://stemcells.nih.gov/fedPolicy/NIHFedPolicy.asp (June 24, 2003)(on file with Court).

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

| | | |
|---|---|---|
| MARY DOE, et al., | * | |
| | * | |
| Plaintiffs | * | |
| | * | |
| v. | * | Civil No. PJM 99-2428 |
| | * | |
| TOMMY G. THOMPSON, Secretary of the Department of Health and Human Services, et al., | * | |
| | * | |
| Defendants | * | |

FINAL ORDER OF JUDGMENT

Upon consideration of the various motions pending in this case, it is, for reasons stated in the accompanying Memorandum Opinion, this 3rd day of July, 2003,

ORDERED:

1) Defendants' Motion to Deny Plaintiffs' Motion for Contempt and [to] Close Case [Paper No. 60] is GRANTED;
2) Plaintiffs' Motion for Contempt [Paper No. 59]; Request to Re-Open the Case [Paper No. 61] and Request for Oral Argument and Judgment on the Pleadings [Paper No. 63] are DENIED;
3) This case is DISMISSED as MOOT; and
4) The Clerk shall CLOSE the case.

/s/
PETER J. MESSITTE
UNITED STATES DISTRICT JUDGE

JUDGMENT

FILED: January 4, 2005

UNITED STATES COURT OF APPEALS

for the

Fourth Circuit

No. 03-2254
CA-99-2428-PJM

MARY DOE, a human embryo "born" in the United States (and subsequently frozen in which state of cryopreservation her life is presently suspended) individually and on behalf of all other frozen human embryos similarly situated

Plaintiff - Appellant

v.

DONNA E. SHALALA, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, in her official capacity as Secretary of Health and Human Services; SOCIAL SECURITY ADMINISTRATION; HAROLD VARMUS, Doctor, in his official capacity as Director of the National Institutes of Health

Defendants - Appellees

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Appeal from the United States District Court for the District of Maryland at Greenbelt

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In accordance with the written opinion of this Court filed this day, The Court affirms the judgment of the District Court.

A certified copy of this judgment will be provided to the District Court upon issuance of the mandate. The judgment will take effect upon issuance of the mandate.

Patricia S. Connor
/s/
CLERK

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT
FILED

January 4, 2005

No. 03-2254
CA-99-2428-PJM

MARY DOE, a human embryo "born" in the United States (and subsequently frozen in which state of cryopreservation her life is presently suspended) individually and on behalf of all other frozen human embryos similarly situated

Plaintiff - Appellant

v.

DONNA E. SHALALA, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, in her official capacity as Secretary of Health and Human Services; SOCIAL SECURITY ADMINISTRATION; HAROLD VARMUS, Doctor, in his official capacity as Director of the National Institutes of Health

Defendants - Appellees

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On Petition for Rehearing and Rehearing En Banc

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The appellant's petition for rehearing and rehearing en banc was submitted to this Court. As no member of this Court or the panel requested a poll on the petition for rehearing en banc, and

As the panel considered the petition for rehearing and is of the opinion that it should be denied,

IT IS ORDERED that the petition for rehearing and rehearing en banc is denied.

Entered at the direction of Judge Luttig, with the concurrence of Judge King and Judge Shedd.

For the Court,
Patricia S. Connor
/s/
CLERK

APPEAL
U.S. District Court
District of Maryland (Baltimore)
CIVIL DOCKET FOR CASE #: 1:99-cv-02428-PJM

| | |
|---|---|
| Doe, et al v. Shalala, et al | Date Filed: 08/10/99 |
| Assigned to: Judge Peter J. Messitte | Jury Demand: None |
| Referred to: | Nature of Suite: 440 Civil |
| Demand: $0 | Rights: Other |
| Lead Docket: None | Jurisdiction: U.S. Government |
| Related Cases: None | Defendant |
| Case in other court: None | |
| Cause: 28:1331 Federal Question: | |
| Other Civil Rights | |

| | |
|---|---|
| Plaintiff | |
| Mary Doe, *a human embryo "born" in the United States (and subsequently frozen in which state of cryopreservation her life is presently suspended) individually and on behalf of all other frozen human embryos similarly situated* | represented by **Rudolph Martin Palmer, Jr.** R. Martin Palmer Attorney at Law 21 Summit Avenue Hagerstown, MD 21740 13017900640 ATTORNEY TO BE NOTICED |
| The National Association for the Advancement of Preborn Children (NAAPC) | represented by **Rudolph Martin Palmer, Jr.** (See above for address) LEAD ATTORNEY ATTORNEY TO BE NOTICED |

v.

Defendant

Donna Shalala, *in her official capacity as Secretary of Health and Human Services*

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| | |
|---|---|
| | 14102094800<br>Fax: 14109622310<br>Email: larry.adams@usdoj.gov<br>LEAD ATTORNEY<br>ATTORNEY TO BE<br>NOTICED |
| Department of Health and Human Services | represented by<br>Allen F. Loucks<br>(see above for address)<br>TERMINATED: 05/09/2001<br>LEAD ATTORNEY<br>ATTORNEY TO BE<br>NOTICED<br><br>Kaye A. Allison<br>(see above for address)<br>LEAD ATTORNEY<br>ATTORNEY TO BE<br>NOTICED<br><br>Larry D. Adams<br>(see above for address)<br>LEAD ATTORNEY<br>ATTORNEY TO BE<br>NOTICED |
| Dr. Harold Varmus,<br>*in his official capacity as Director of the NationalInstitutes of Health* | represented by<br>Allen F. Loucks<br>(see above for address)<br>TERMINATED: 05/09/2001<br>LEAD ATTORNEY<br>ATTORNEY TO BE<br>NOTICED |

| | |
|---|---|
| | Kaye A. Allison<br>(see above for address)<br>LEAD ATTORNEY<br>ATTORNEY TO BE<br>NOTICED<br><br>Larry D. Adams<br>(see above for address)<br>LEAD ATTORNEY<br>ATTORNEY TO BE<br>NOTICED |
| National Institutes of Health | represented by<br>Allen F. Loucks<br>(See above for address)<br>TERMINATED: 05/09/2001<br>LEAD ATTORNEY<br>ATTORNEY TO BE<br>NOTICED<br><br>Kaye A. Allison<br>(see above for address)<br>LEAD ATTORNEY<br>ATTORNEY TO BE<br>NOTICED<br><br>Larry D. Adams<br>(see above for address)<br>LEAD ATTORNEY<br>ATTORNEY TO BE<br>NOTICED |

| Filing Date | # | Docket Text |
|---|---|---|
| 08/10/1999 | 1 | COMPLAINT filed; FILING FEES $150.00 RECEIPT #B160027 (mdd, Deputy Clerk)(Entered: 08/11/1999) |
| 08/10/1999 | 2 | MOTION by Mary Doe to recuse the ordinary requirement for the Appointment of guardian ad litem, or in the alternative to appoint such a guardian. (c/s)(mdd, Deputy Clerk)(Entered: 08/11/1999). |
| 08/10/1999 | 3 | MEMORANDUM by Mary Doe in support of her [2-1] motion to recuse the ordinary requirement for the appointment of guardian ad litem, and [2-2] motion to appoint such a guardian by Mary Doe (mdd, Deputy Clerk)(Entered: 08/11/1999) |
| 08/10/1999 | 4 | SUMMONS(ES)(60 days) issued for Donna Shalala, Department of Health, Dr. Harold Varmus, National Institutes. (ISSUED BY DEPUTY CLERK MW)(mdd, Deputy Clerk) Modified on 08/11/1999) (Entered: 08/10/1999) |
| 08/25/1999 | | CASE reassigned from Judge Motz to Judge Peter J. Messitte (cag, Deputy Clerk)(Entered: 08/27/1999) |
| 08/27/1999 | 5 | CORRESPONDENCE of case reassignments to Judge Messitte sent to all parties. (mms, Deputy Clerk)(Entered: 08/27/1999) |
| 09/02/1999 | 6 | RETURN OF SERVICE executed as to Donna Shalala 08/10/99. Answer due on 10/9/99 for Donna Shalala (td, Deputy Clerk)(Entered: 09/09/1999) |

| | | |
|---|---|---|
| 09/02/1999 | 7 | RETURN OF SEVICE executed as to Donna Shalala, National Institutes 8/12/99; Answer due on 10/11/99 for Donna Shalala, for National Institutes; and Attachments (td, Deputy Clerk) (Entered: 09/09/1999) |
| 09/02/1999 | 8 | RETURN OF SERVICE executed as to Department of Health, Dr. Harold Varmus 8/13/99; Answer due on 10/12/99 for Department of Health, for Dr. Harold Varmus; and Attachments (td, Deputy Clerk) (Entered: 09/09/1999) |
| 09/17/1999 | 9 | LETTER/ORDER "REQUESTING" that the Government Submit a Written Response within 20 days hereof to Mr. Palmer's Letter requesting Judge Messitte Recuse himself; and "EXTENDING" the Time for the Government's Answer and Opposition to Plaintiff's Motion until such time as the Judge Decides the Issue of his own Recusal (signed by Judge Peter J. Messitte 9/15/99) (c/m 9/17/99 kc) (td, Deputy Clerk) (Entered: 09/20/1999) |
| 10/15/1999 | 10 | LETTER/REQUEST by Plaintiff's Counsel for Recusal of Judge Messitte (rec'd in chambers on 9/7/99) (copy) (td, Deputy Clerk) (Entered: 10/19/1999) |
| 10/15/1999 | 11 | RESPONSE by Defendants to [10-1] motion for Recusal of Judge Messitte by Plaintiffs (rec'd in chambers on 10/12/99) (td, Deputy Clerk) (Entered: 10/19/1999) |

| | | |
|---|---|---|
| 10/15/1999 | 12 | LETTER/ORDER "DENYING" [10-1] motion of Plaintiffs for Recusal as therein set forth (signed by Judge Peter J. Messitte 10/14/99) (c/m 10/15/99 esp) (td, Deputy Clerk) (Entered: 10/19/1999) |
| 11/10/1999 | 13 | MOTION by Mary Doe to Reassign to Original Jurist i and attachment (c/s) (lad, Deputy Clerk) (Entered: 11/16/1999) |
| 11/10/1999 | 14 | RESPONSE by Donna Shalala, Department of Health, Dr. Harold Varmus, National Institutes to [13-1] motion to Reassign to Original Jurist by Mary Doe (c/s) (lad, Deputy Clerk) (Entered: 11/16/1999) |
| 11/16/1999 | 15 | REPLY by Mary Doe to Defendants' Response to her [13-1] motion to Reassign to Original Jurist and Attachments (c/s) (td, Deputy Clerk) (Entered: 11/17/1999) |
| 12/01/1999 | 16 | MEMORANDUM/ORDER "DENYING" [13-1] motion of Plaintiff to Reassign to Original Jurist; and "DIRECTING" Defendants to File an Answer to the Complaint and a Response to Plaintiffs' Motion to Recuse the Ordinary Requirement for the Appointment of Guardian Ad Litem, or in the alternative, to Appoint Such a Guardian by 12/30/99 (signed by Judge Peter J. Messitte 11/30/99) (c/f 12/3/99) (td, Deputy Clerk) (Entered: 12/03/1999) |
| 01/05/2000 | 17 | MOTION with memorandum in support by Defendants to Dismiss or, in the alternative, for Summary Judgment and Request for Hearing (1 c/s)(td, Deputy Clerk)(Entered: 01/07/2000) |

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| 01/11/2000 | 18 | RESPONSE by Defendants in opposition to [2-1] motion to recuse the ordinary requirement for the appointment of guardian ad litem and [2-2] motion to appoint such a guardian by Mary Doe (1 c/s)(td, Deputy Clerk)(Entered: 01/21/2000) |
| 01/12/2000 | 19 | MEMORADUM Confirming that Argument on Defendants' Motion to Dismiss or, in the alternative, for Summary Judgment has been set for 2/28/2000 at 2:00pm (c/m 1/11/2000 esp)(td, Deputy Clerk)Modified on 01/21/2000(Entered: 02/13/2000) |
| 01/13/2000 | 20 | REQUEST by Mary Doe for Hearing on Motion to Reassign to Original Jurist (c/s)(td, Deputy Clerk) Modified on 01/21/2000 (Entered: 01/18/2000) |
| 01/18/2000 | 21 | MOTION by Plaintiffs for Entry of Default as to Donna Shalala, Department of Health, Dr. Harold Varmus and National Institutes (c/s) (td, Deputy Clerk) Modified on 01/21/2000 (Entered: 01/19/2000) |
| 01/20/2000 | 22 | ORDER "DEEMING" MOOT [20-1] Request of Plaintiff for Hearing on Motion to Reassign to Original Jurist (signed by Judge Peter J. Messitte 1/19/2000)(c/m 1/19/2000 rs & kc) (c/i 1/21/2000)(td, Deputy Clerk) (Entered: 01/21/2000) |
| 01/20/2000 | 23 | RESPONSE by Defendants in opposition to [13-1] motion to Reassign to Original Jurist by Mary Doe (c/s) (td, Deputy Clerk) (Entered: 01/24/2000) |

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| 02/02/2000 | 24 | MEMORANDUM/ORDER "CLARIFYING" the Status of the Case as understood by the Court; "STATING" that the Second Motion to Reassign to Original Jurist will be docketed as Paper #25; "DENYING" [25-1] Second Motion to Reassign to Original Jurist with prejudice, "DENYING" [21-1] motion of Plaintiff for Entry of Default as to Donna Shalala, Department of Health. Dr. Harold Varmus and National Institutes, and "STATING" that the pending Motions will be heard on 2/28/2000 at 2:00 p.m.; and Attachment (signed by Judge Peter Messitte 2/1/2000) (c/m 2/9/2000 td) (c/i 2/9/2000) (td, Deputy Clerk) Modified on 02/09/2000 (Entered: 02/09/2000) |
| 02/02/2000 | 25 | MOTION by Mary Doe to Reassign Original Jurist (unsigned) (originally received on 1/18/2000, but not placed on docket) (td, Deputy Clerk) (Entered: 02/09/2000) |
| 02/15/2000 | 26 | RESPONSE by Plaintiff to [17-1] motion to Dismiss or, in the alternative, [17-2] motion for Summary Judgment by National Institutes, Dr. Harold Varmus, Department of Health and Donna Shalala, Attachments A thru D and Memorandum (c/s) (td, Deputy Clerk) (Entered: 02/17/2000) |
| 02/24/2000 | 27 | SUPPLEMENT by Mary Doe to her [26-1] Response (Reply) to Defendants' Motion to Dismiss or, in the alternative, for Summary Judgment, Affidavit, and Curriculum Vitae of Clayton Ward Kischer, Ph.D. (Curriculum received on 2/28/2000) (c/s) (td, Deputy Clerk) Modified on 02/29/2000 (Entered: 02/25/2000) |

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| 02/28/2000 | | Motion hearing held before Messitte, J. re: [17-1] motion of Defendant to Dismiss, or in the alternative [17-2] motion for Summary Judgment-Argued-"TAKEN UNDER ADVISEMENT" (Court Reporter: Simpkins) (td, Deputy Clerk) (Entered: 02/29/2000) |
| 02/28/2000 | 28 | Exhibit list by Plaintiffs (td, Deputy Clerk) (Entered: 02/29/2000) |
| 03/01/2000 | 29 | COURT REQUESTED SUPPLEMENTAL MEMORANDUM concerning the Legislative History, Status, and NIH Complaint with the Current Law respecting Prohibition of Federal Funds for Human Embryo Experimentation and Research by Mary Doe, and Exhibits A thru F (c/s) (td, Deputy Clerk) Modified on 03/02/2000 (Entered: 03/02/2000) |
| 03/07/2000 | 30 | RESPONSE by Defendants to Plaintiff's [29-1] Post-Trial Memorandum and Attachments (1 c/s) (td, Deputy Clerk) (Entered 03/09/2000) |
| 03/10/2000 | 31 | OBJECTION by Mary Doe to Defendants' [30-1] Response to Plaintiffs' Post-Trial Memorandum (c/s) (td, Deputy Clerk) (Entered: 03/13/2000) |
| 08/28/2000 | 32 | MEMORANDUM /ORDER "REQUESTING" Parties to File Supplemental Briefs to Defendant's Motion to Dismiss incorporating specifics from the Guidelines for Research Using Human Pluripotent Stem Cells within 30 days of the date of this Order (signed by Judge Peter J. Messitte 8/25/2000) (c/i 8/29/2000) (td Deputy Clerk) (Entered: 08/29/2000) |

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| 09/22/2000 | 33 | PLAINTIFF'S COURT REQUESTED SUPPLEMENTAL BRIEF to [17-1] motion to Dismiss by Defendants concerning the Issuance of Guidelines for Research using Human Pluripotent Stem Cells on 8/23/2000 by the National Institutes of Health and Attachments A thru D (c/s) (td, Deputy Clerk) (Entered: 09/22/2000) |
| 09/22/2000 | 34 | REQUEST by Mary Doe for Injunction Precluding the National Institutes of Health from Implementing Guidelines for Research Using Human Pluripotent Stem Cells Issued on 8/23/2000 (c/s) (td, Deputy Clerk) (Entered: 09/22/2000) |
| 09/25/2000 | 35 | SUPPLEMENTAL MEMORANDUM of Defendants in support of their [17-1] motion to Dismiss or, in the alternative, [17-2] motion for Summary Judgment and Attachment (1 c/s) (td, Deputy Clerk) (Entered: 09/25/2000) |
| 10/05/2000 | 36 | MOTION by defendants for Extension of Time to file their opposition to plaintiff's Motion for Preliminary Injunction to and including 10/19/00 (c/s) (ajh, Deputy Clerk) (Entered: 10/06/2000) |
| 10/11/2000 | 37 | ORDER "GRANTING" [36-1] motion of Defendants for Extension of Time to file their opposition to plaintiff's Motion for Preliminary Injunction to and including 10/19/00 (signed by Judge J. Messitte 10/10/2000) (c/m 10/11/2000 pf) (c/i 10/12/2000) (td, Deputy Clerk) (Entered: 10/12/2000) |

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| 10/19/2000 | 38 | RESPONSE by Defendants in opposition to [34-1] Request for Injunction Precluding the National Institutes of Health from Implementing Guidelines for Research Using Human Pluripotent Stem Cells Issued on 8/23/2000 by Mary Doe, and Attachments 1 & 2 (c/s) (td, Deputy Clerk) (Entered: 10/23/2000) |
| 10/23/2000 | 39 | REPLY by Mary Doe to Defendants' [35-1] Supplemental Brief in support of their Motion to Dismiss or, in the alternative, for Summary Judgement (c/s) (td, Deputy Clerk) (Entered: 10/23/2000) |
| 10/31/2000 | 40 | MEMORANDUM confirming that a Hearing on Plaintiffs' Request for Injunction and Defendants' Opposition thereto has been set (c/m 10/31/2000 esp) (td, Deputy Clerk) (Entered: 11/01/2000) |
| 11/02/2000 | 41 | MEMORANDUM stating that the Hearing set for 12/7/2000 will include the Request for Injunction and the Pending Motion for Summary Judgment (c/m 11/3/2000 td) (td, Deputy Clerk) (Entered: 11/03/2000) |
| 11/09/2000 | 42 | MEMORANDUM rescheduling the Hearing on Pending Motions (c/m 11/9/2000 esp) (td, Deputy Clerk) (Entered: 11/09/2000) |
| 12/05/2000 | 43 | MEMORANDUM requesting Plaintiff's Counsel to initiate the conference call to chambers to reset the Hearing on Pending Motions (c/m 12/4/2000 esp) (td, Deputy Clerk) (Entered: 12/05/2000) |

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| 12/11/2000 | 44 | MEMORANDUM confirming that the Hearing on Pending Motions has been reset (c/m 12/1/2000 esp) (td, Deputy Clerk) (Entered: 12/11/2000) |
| 01/23/2001 | 45 | MEMORANDUM confirming that the Motions Hearing originally scheduled for 2/5/2001 has been reset (c/m 1/23/2001 esp) (td, Deputy Clerk) (Entered: 01/24/2001) |
| 02/26/2001 | | Motion hearing held before Messitte, J. re: [17-1] motion to Dismiss, [17-2] motion for Summary Judgment, [34-1] motion for Injunction Precluding the National Institutes of Health from Implementing Guidelines for Research Using Human Pluripotent Stem Cells Issued on 8/23/2000 – Argued (Court Reporter: Simpkins) (lad, Deputy Clerk) (Entered: 02/27/2001) |
| 02/26/2001 | 46 | Supplemental MEMORANDUM by Mary Doe, National Association in support of [34-1] motion for Injunction Precluding the National Institutes of Health from Implementing Guidelines for Research Using Human Pluripotent Stem Cells Issued on 8/23/2000 (c/s) (lad, Deputy Clerk ) (Entered: 02/27/2001) |
| 02/26/2001 | 47 | MEMORANDUM by Mary Doe, National Association in support of [34-1] motion for Injunction for Precluding the National Institutes of Health from Implementing Guidelines for Research using Human Pluripotent Stem Cells Issued on 8/23/2000 (c/s) (lad, Deputy Clerk) (Entered: 02/27/2001) |

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| 02/26/2001 | 48 | Exhibit list by Mary Doe, National Association (lad, Deputy Clerk) (Entered: 02/27/2001) |
| 02/26/2001 | 49 | Exhibit list by Donna Shalala, Department of Health, Dr. Harold Varmus, National Institutes (lad, Deputy Clerk) (Entered: 02/27/2001) |
| 02/26/2001 | | Oral ORDER "ADMINISTRATIVELY" Closing Case for reasons stated by the Court (by Judge Peter J. Messitte) (lad, Deputy Clerk) (Entered: 02/27/2001) |
| 02/26/2001 | | Case closed (lad, Deputy Clerk) (Entered: 02/27/2001) |
| 02/26/2001 | 50 | MEMORANDUM "ADMINISTRATIVELY" Closing this Case as therein set forth (signed by Judge Peter J. Messitte) (c/i 2/26/01) (lad, Deputy Clerk) (Entered: 02/27/2001) |
| 02/26/2001 | 52 | NOTICE OF APPEAL by Mary Doe. Fee Status: $105.00 filing fee paid Appeal record due on 3/28/01 (mlb, Deputy Clerk) (Entered: 02/28/2001) |
| 02/27/2001 | 51 | MOTION by Donna Shalala, Department of Health , Dr. Harold Varmus, National Institutes to Continue Hearing for 60 days (rec'd in Baltimore 2/23/01) (lad, Deputy Clerk) (Entered: 02/27/2001) |
| 02/28/2001 | | Notice of appeal and certified copy of dockets to USCA: [52-1] appeal by Mary Doe (mlb, Deputy Clerk) (Entered: 02/28/2001) |
| 03/09/2001 | | USCA Case Number Re: [52-1] appeal by Mary Doe USCA NUMBER: 01-1298 (Case Mgr. Shirley J. Beasley) (mlb, Deputy Clerk) (Entered: 03/12/2001) |

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| 05/09/2001 | 53 | MOTION by defendants to Substitute Attorney Allen Loucks (ajh, Deputy Clerk) (Entered: 05/10/2001) |
| 05/09/2001 | 54 | ORDER "GRANTING" defendants [53-1] motion to Substitute Attorney Allen Loucks terminated attorney Allen F. Loucks for National Institutes, for Dr. Harold Varmus, for Department of Health, for Donna Shalala; Added Larry D. Adams (signed by Judge Deborah K. Chasanow 5/8/01) (c/m 5/9/01 esp) (c/i 5/10/01) (ajh, Deputy Clerk) (Entered: 05/10/2001) |
| 06/04/2001 | 54 | TRANSCRIPT filed [52-1] appealed by Mary Doe for dates of 2/26/00 and 2/28/00 Appeal record due on 6/19/01 (mlb, Deputy Clerk) (Entered: 06/05/2001) |
| 06/19/2001 | 55 | Certificate of Clerk certifying record as complete for appeal purposes for [52-1] appeal by Mary Doe (pkf, Deputy Clerk) (Entered: 06/19/2001) |
| 06/22/2001 | 56 | SECOND STATUS REPORT by Department of Health (rank, Deputy Clerk) Entered: 06/28/2001) |
| 04/12/2002 | 57 | ORDER (copy) from United States Court of Appeals for the Fourth Circuit "DENYING" the petition for rehearing. (c/s 1/12/02 pf) (pkf, Deputy Clerk) (Entered: 04/12/2002) |
| 04/18/2002 | 58 | JUDGEMENT OF USCA (certified copy) "DISMISSING" the appeal Re: [52-1] appeal by Mary Doe (mlb, Deputy Clerk) (Entered: 04/18/2002) |
| 10/22/2002 | 59 | MOTION by Mary Doe, National Association for Contempt (c/s) (mib, Deputy Clerk) (Entered: 10/22/2002) |

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| 10/25/2002d | 60 | MOTION by Donna Shalala, Department of Health, Dr. Harold Varmus, National Institutes to Deny Plaintiff's Motion for Contempt and Close Case (c/s) (mib, Deputy Clerk) (Entered: 10/28/2002) |
| 10/31/2002 | 61 | RESPONSE by Mary Doe, National Association to [60-1] motion to Deny Plaintiff's Motion for Contempt and Close Case by National Institutes, Dr. Harold Varmus, Department of Health, Donna Shalala and Exhibit A (c/s) (mib, Deputy Clerk) (Entered: 10/31/2002) |
| 10/31/2002 | 61 | MOTION by Mary Doe To Reopen Case (c/s) (mib, Deputy Clerk) (Entered: 10/31/2002) |
| 11/01/2002 | 62 | MEMORANDUM by Mary Doe in support of [61-1] motion response by National Association, Mary Doe and Attachments (c/s) (mib, Deputy Clerk) (Entered: 11/01/2002) |
| 11/08/2002 | 63 | MOTION by Mary Doe, National Association To Reopen Case for Oral Argument and Judgment on the Pleadings (c/s) (mib, Deputy Clerk) (Entered: 11/08/2002) |
| 07/03/2003 | 64 | MEMORANDUM OPINION. Signed by Judge Peter J. Messitte on 7/3/03. (rank, Deputy Clerk) (Entered: 07/08/2003) |
| 07/03/2003 | 65 | ORDER, granting [60] Motion by defendant to Deny Plaintiffs' Motion for Contempt and to Close Case; Motion denying [59] for contempt by plaintiff; Request to Re-Open the Case [61-1], and Request for Oral Argument and Judgement on the pleadings [63-1]: "DISMISSING" this Case as MOOT; and "DIRECTING" the Clerk to CLOSE this case. Signed by Judge Peter J. Messitte on |

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| | | 7/3/03. (rank, Deputy Clerk) (Entered: 07/11/2003) |
| 07/14/2003 | 66 | MOTION/Petition for Reconsideration for Case Closure by Mary Doe, The National Association for the Advancement of Preborn Children (NAAPC) and attachments (c/s) (ajh, Deputy Clerk) (Entered: 07/15/2003) |
| 08/05/2003 | 67 | ORDER denying [66] Motion for Reconsideration of Case Closure Signed by Judge Peter J. Messitte on 8/5/03. (rank, Deputy Clerk) (Entered: 08/07/2003) |
| 10/03/2003 | 68 | NOTICE OF APPEAL as to 67 Order on Motion for Miscellaneous Relief by Mary Doe. (no filing fee paid) Appeal Record due by 11/3/2003. (mlb, Deputy Clerk) (Entered: 10/07/2003) |
| 10/07/2003 | | Transmission of Notice of Appeal and Docket Sheet to US Court of Appeals re [68] Notice of Appeal (mlb, Deputy Clerk) (Entered: 10/07/2003) |

CERTIFICATE OF SERVICE

I hereby affirm that a copy of the foregoing Docketing Sheet was mailed, postage prepaid to Larry Adams and Kaye Allison. US Attorneys for Appellees, 101 W. Lombard Street, 6th Floor, Baltimore, MD 21201 on this 16th day of October, 2003.

_____/s/_____

R. Martin Palmer

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
BALTIMORE, MARYLAND

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| MARY DOE, a human embryo "born" in the United States (and subsequently frozen in which state of cryopreservation her life is presently suspended), individually and on behalf of all other frozen human embryos similarly situated; and the National Association for the Advancement of Preborn Children (NAAPC), | ) | Civil Action No. CFM 99-2428 |
| Plaintiffs, | ) | |
| vs. | ) | |
| DONNA SHALALA, in her official capacity as Secretary of Health and Human Services; DEPARTMENT OF HEALTH AND HUMAN SERVICES; DR. HAROLD VARMUS, in his official capacity as Director of the National Institute of Health and, NATIONAL INSTITUTES OF HEALTH, | ) | COMPLAINT |
| Defendants. | ) | |

Plaintiffs, by way of complaint against the Defendants, allege the following:

## NATURE OF ACTION

1. This is an action for declaratory, injunctive and other appropriate relief, brought under the Declaratory Judgment Act, 28 U.S.C. Section 551 et seq., and seeking (a) the entry of a declaratory judgment that Mary Doe, as a citizen of the United States of America, is entitled to the equal protection of the laws thereof and that the President's Advisory Commission and the National Institutes of Health violate Mary Doe's rights under the Fourteenth Amendment to the United States Constitution by issuing and/or implementing recommendations for human embryo experimentation; which result in her certain and sudden death, and (b) the entry of an injunction ordering the current administration, the Department of Health and Human Services and the National Institutes of Health to cease and desist any and all plans to undertake human embryo (stem cell) experimentation.

## JURISDICTION AND VENUE

2. Jurisdiction over this action is conferred by the federal question jurisdiction statute 28 U.S.C. Section 1331.

3. Venue is properly reposed in this Court by virtue of 28 U.S.C. Section 1391(e).

## PARTIES

4. Plaintiff Mary Doe is a human embryo "born" (produced or brought into life) in the United States, as that

term is defined in the Fourteenth Amendment to the United States Constitution (and specifically as the word "born" is defined in Webster's Dictionary. Complete and Unabridged, of 1857, contemporaneous with the passage of the Fourteenth Amendment (1868).

5. Plaintiff National Association for the Advancement of Preborn children is an organization dedicated to the advocacy for the equal humanity and personhood of preborn children, including "children *in vitro*," with offices located in Hagerstown, Maryland.

6. Defendant Donna Shalala is currently the Secretary of Health and Human Services and is the head of the Department of Health and Human Services.

7. Defendant Department of Health and Human Services is an agency within the Executive Branch of the federal government.

8. Defendant Dr. Harold Varmus is currently the Director of National Institutes of Health, who has his office in Bethesda, Maryland.

9. Defendant National Institues of Health is a division within the Department of Health and Human Services, with offices located in Bethesda, Maryland.

FACTUAL EXPLANATION OF THE EQUAL HUMANITY AND PERSONHOOD OF MARY DOE

10. That Mary Doe is a human embryo "produced or

brought into life" by the new science of *in vitro* (Latin for "in glass") fertilization whereby the process of fertilization, which produces or brings her into life, takes place not in the tube of flesh (the fallopian tube) but in a tube of glass (the test tube); after which life for her has been suspended by the freezing of Mary Doe in liquid nitrogen (cryo-preservation).

11. That the modern science of *in vitro* fertilization allows Mary Doe to be returned to the warmth of life, after storage for months or years in a frozen state, and implanted in the womb of an adopting mother as a "child *in vitro*."

12. That the modern science of *in vitro* fertilization has given rise to the adoption of "children *in vitro*" as human embryos, and Mary Doe, on behalf of herself as a frozen human embryo and all others similarly situated, prays an injunction against her use for human embryo experimentation (stem cell research) which would result in her certain death so that she might, in place of death, be given the opportunity of adoption as a "child *in vitro*" and her life, which has temporarily been brought to a standstill in the deep freeze, would be allowed to resume upon returning her to the warmth of life and the loving option of adoption as a "child *in vitro*" so that she might fulfill her destiny.

13. That everything necessary to build Mary Doe is present, sufficient, and complete from the very beginning. Nothing is added. Everything necessary to build the human

brain, capable of going to the moon and putting foot upon the moon, is locked in at the moment of fertilization.

14. That such a realization is too wonderful for man. It is high; he cannot attain unto it.

15. That science now proves to man the truth of his being from the very beginning – as a newly conceived (fertilized) human being.

16. That science now proves to man that he is fearfully and wonderfully made; the creation of God.

17. That Mary Doe's forefather's truly stated in the Declaration of Independence, the charter of her nation, that ". . . all mean are CREATED (by God) equal and endowed by their CREATOR with certain unalienable rights, that among these are life, liberty, and the pursuit of happiness."

18. That Mary Doe by virtue of her equal creation claims her equal right to life, liberty, and the pursuit of happiness.

19. That included within Mary Doe's right to life, liberty, and the pursuit of happiness is her right to be adopted by a married couple wishing to adopt a frozen human embryo (a "child *in vitro*"), at which time Mary Doe is removed from the deep freeze of cryo-preservation and returned to the warmth of life, being implanted in the adopting mother's womb.

20. That Mary Doe then begins her nine month journey within the "innerspace" of the vaulted temple of the womb with its filtered reddish light (curiously much like the filtered light

of a stained glass cathedral that man later builds himself).

21. That Mary Doe's entire substance is seen and known to her Creator when she is yet unformed, and in her Creator's book all her members are written, which in continuance are fashioned, when as yet there are none of them.

22. That Mary Doe, as a human embryo, has been produced or brought into life from the moment of her conception (fertilization).

23. That the 1857 edition of Webster's Dictionary defines "born" as: "produced or brought into life." (A copy of the title pages and definition page of said Webster's Dictionary [available in the Library of Congress] is attached hereto and made a part hereof).

24. That newly discovered scientific evidence causes this old definition of "born" found in Webster's Dictionary contemporaneous with the passage of the Fourteenth Amendment (1868) to be more accurate than the definition of "born" found in the modern dictionary, for Mary Doe has truly been produced or brought into life" at the moment of her conception as a human embryo. Mary Doe proves this to man over and over again when she is frozen by the technician, stored in such a frozen state (cryo-preservation) for months or years, taken out of the freezer and shipped, while still frozen, by overnight express to another city where she may be implanted in the womb of an adopting mother. (The Court will be able to take judicial notice

that at the close of the twentieth century we now have mothers carrying to term their own daughter's child, such that the grandmother's temple of the womb offers temporary shelter to her granddaughter conceived by that grandmother's daughter.

25. That the Court may likewise take judicial notice of the fact that there is no requirement that a frozen human embryo be returned to the womb of her genetic mother to continue to grow, but rather the newly (fertilized) human embryo may be offered shelter in the womb of an adopting mother.

26. That the court can take judicial notice of the fact that adoption of frozen embryos is a common occurrence, and that entire organizations have come into being and now exist to bring together frozen human embryos and prospective adoptive parents (the Christian Adoption and Family Services of California being one such organization).

27. That complete and sufficient within Mary Doe is the ability to build herself – like a little astronaut in "innerspace" (of the temple of the womb) Mary Doe hooks onto the wall of the womb for nutrients and oxygen and builds and extends her own little astronaut lifeline (placenta) through which she will continue to receive nutrients and oxygen with which to build the temple of her body, which will be nine months in completion.

28. That for the purpose of building the temple of her body Mary Doe builds a little bubble spacesuit around herself

for her journey in "innerspace" until she passes a chemical message over her placenta back to the body of her "mothership" signaling and initiating in her mother's body the contractions of "labor" which will "deliver" Mary Doe from the innerspace of the 'temple of the womb' to the outerspace of the sunshine of her fellow humanity.

29. That at the close of the twentieth century even skeptics are made to understand that Mary Doe is a being; and being human, she is a human being; she is 'person' and not 'property' because she is the only property which has the "property" of building herself, even the human brain capable of going to the moon and setting foot on the moon.

30. That when frail humanity considers how fearfully and wonderfully Mary Doe is made, man, who is truly understanding, comes to realize that Mary Doe as a human embryo figuratively glows with a white hot incandescence, having just been released from the fingertip of God.

31. That, as such, Mary Doe is given to receive the reverential respect of man; and she is given to receive the equal respect of the high constitutional ideals and protection of the laws of the United States of America.

32. That to deny such equal protection to Mary Doe is to ultimately deny the protection of the Constitution to all Americans; for in denying Mary Doe the equal protection of the laws we pull the sanctity of life thread that permeates all of life.

33. That if we ask Science: "What is a human being?", Science responds: "A human being is a member of our species." And if we ask Science: "What is a preson?", Science responds: "A person is a human being alive." And Science has no other answer.

34. That if we tour a temple or cathedral, not knowing the builder, we recognize it to be the manifestation of rational thought and plan. The temple is not a person; but a person (a human being alive, capable of rational thought) designed and build the cathedral.

35. That likewise, when we contemplate the fearful wonder of Mary Doe who will build for herself the wondrous temple of the body, we realize such a cathedral to be a manifestation of rational thought and plan. It was built by a person, capable of rational thought.

36. That if we acknowledge that the builder of the temple of Mary Doe's body is, in fact, God, Mary Doe is entitled to reverential respect as a creation of God.

37. That if we choose to deny that it is God who fashions Mary Doe and knits together the temple of her body, then and in that event we are left only with Mary Doe who must be her own builder, fashioning together herself; even the human brain capable of going to the moon and setting foot on the moon is then built by Mary Doe, possessed of a truly rational nature. As such Mary Doe is, in and of herself, "a person" as that term

is defined in Webster's 1857 Dictionary: 1. An individual human being consisting of body and soul. We apply the word to living beings only, possessed of a rational nature; the body when dead is not called a person. It is applied alike to man, woman, or child. 2. A man, woman, or child, considered as opposed to things, or distinct from them. 3. A human being, considered with respect to the living body or corporeal existence only. The form of her person is elegant. 4. A human being indefinitely; one; a man. Let a person's attainments be never so great, he should remember he is frail and imperfect."

38. That there is no countervailing personhood with constitutional rights that allegedly overshadows Mary Doe's personhood and constitutional rights (this is not an abortion case).

39. That if we correctly understand that it is God who builds Mary Doe's temple of a body, then we believe in God and must reverentially honor and respect Mary Doe as a creation of God, and we understand that we must do unto Mary Doe as we would have Mary Doe do unto us if she were the adult lab technician about to choose between vivisecting and experimenting upon us as a human embryo or giving us over instead to the loving opportunity of adoption as a "child *in vitro*."

FACTUAL BACKGROUND OF THE CASE

40. On July 13, 1999 a Presidential Advisory Commission (stacked in favor of human embryo experimentation) concluded

that federally funded scientists should be allowed to use "donated" (by whom and by what authority are human beings being bartered and sold and at what price?) human embryos for bio-medical research.

41. That Mary Doe respectfully proffers that she has the opportunity to be adopted as a 'child in vitro' by virtue of the fact that adoption of frozen human embryos is a growing, current and ongoing factual occurrence in the United States and many organizations have been formed in the nation coordinating the bringing together of 'children in vitro' and childless couples who wish to adopt a 'child in vitro', which would afford Mary Doe the opportunity to be implanted in an adoptive mother's womb so that she might fulfill her destiny.

42. That all past presidential administrations have banned human embryo experimentation.

43. That the current administration and the defendants in the recent past undertook to begin human embryo experimentation and the United States Congress, as a part of stopgap spending bills, added the proviso that no federal funds be used for human embryo experimentation. The attempt by the defendants to come in the back door and begin human embryo experimentation was thereby closed.

44. That the defendants have opined that in their opinion "Stem cell research" (stem cells are extracted from living human embryos) does not fall under the Congressional ban

against use of federal funds for human embryo experimentation. Having been barred at the back door, the defendants are now trying to climb in the back window and they have one leg through the window.

45. That the utilitarian thinking underlying the defendant's proposed human embryo experimentation (stem cell research) is what led to Nazi experimentation during World War II (and of all the experiments performed upon human beings by the Nazis - and they had an unlimited number available to them in the concentration camps - not a single advance for medical science resulted). The United States government now seeks similarly to begin experimentation on human embryos confined to the concentration can of the liquid nitrogen, the wall of which also imprisons innocents (just as the wall of the concentration camp imprisoned innocents). This same utilitarian thinking led the United States government to the radiation experiments during the Cold War.

46. That despite this recent history, the Department of Health and Human Services stands poised to release research grants to experimenters who will begin human embryonic stem cell experimentation.

47. That to relegate Mary Doe to human embryo experimentation (stem cell research) is to make a slave of Mary Doe – in violation of the prohibition against slavery under the Thirteenth Amendment to the United States Constitution.

## COUNT ONE – THE PRESIDENT'S ADVISORY COMMISSION RECOMMENDATIONS FAIL TO RECOGNIZE MARY DOE'S EQUAL HUMANITY AND PERSONHOOD AND, THEREFORE, VIOLATE HER FOURTEENTH AMENDMENT RIGHTS TO EQUAL PROTECTION AND THE DUE PROCESS OF LAW

48. That Mary Doe hereby asserts and reiterates the rights enunciated by her forefathers in the Declaration of Independence (the 'charter' of this her nation) who asserted for all then current and future generations that: ". . . all men are CREATED (by God) equal and endowed by their CREATOR with certain unalienable rights, that among these are life, liberty, and the pursuit of happiness. . ." and that her forebearer and previous President of the United States, Abraham Lincoln pointed to these words in challenging the decision of the United States Supreme Court in (Dred) Scott v. Sanford, 60 U.S. 393. In doing so, President Lincoln went over the head of the United States Supreme Court which had wrongly disavowed the equal humanity and personhood of the Negro slave (black man).

49. That following the Civil War and the death of Abraham Lincoln the people of the United States adopted the Fourteenth Amendment to the United States Constitution (1868), which provides in pertinent part:

> " All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein

they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws."

50. That Mary Doe, on behalf of herself and all others similarly situated, respectfully proffers unto this Honorable Court that she has been "produced or brought into life as a child *in vitro*" and as such is a citizen of the United States and of the State wherein she resides in a state of cryo-preservation.

51. That Mary Doe, as a citizen of the United States, should be recognized by the Presidential Advisory Commission and others in the current administration as having equal humanity and personhood with other citizens.

## COUNT TWO – HUMAN EMBRYO EXPERIMENTATION RESULTS IN THE CERTAIN DEATH OF MARY DOE AND, THEREFORE, VIOLATES HER FOURTEENTH AMENDMENT RIGHTS TO EQUAL PROTECTION AND THE DUE PROCESS OF LAW

52. Plaintiffs hereby incorporate the allegations of Paragraphs 1 through 51 as if fully set forth herein at length.

53. That Mary Doe respectfully prays and implores this Honorable Court that she be afforded the equal protection of the laws available to her under the Fourteenth Amendment of

the United States Constitution and that she not be deprived of her opportunity for continued life, and liberty from the 'concentration can' of the liquid nitrogen without due process of the law.

54. That human embryo experimentation results in the certain sudden and instant death of Mary Doe and, therefore, is a deprivation of her rights under the Fourteenth Amendment and she is deprived of those rights when her equal humanity and personhood is not recognized by the current administration and the National Institutes of Health, when they recommend allowing her death through human embryo experimentation.

55. Mary Doe respectfully prays, on behalf of herself and all others similarly situated, that those who covet her life for purposes of experimentation upon her as a human embryo be enjoined from doing so to preserve and protect the lives of Mary Doe and all others similarly situated, in existence as human embryos; and Mary Doe prays that this Honorable Court cause to be entered up an injunction against the defendants, said injunction to prohibit the donation or use of Mary Doe and all other frozen embryo similarly situated for stem cell research or human embryo experimentation.

WHEREFORE, Plaintiffs pray:

(a) That this Honorable Court declare the equal humanity and personhood of Mary Doe and grant her equal protection and due process of the laws, as a citizen of the United States entitled to the equal protection of the laws thereof.

(b) That this Honorable Court find that the President's Advisory Commission recommendations fail to recognize Mary Doe's equal humanity and personhood and, therefore, violate her rights to equal protection and the due process of law.

(c) That this Honorable Court declare that human embryo experimentation results in the certain and sudden death of Mary Doe and, therefore, violates her Fourteenth Amendment rights to equal protection and the due process of law.

(d) That this Honorable Court issue an injunction against the Defendants ordering them to cease and desist any and all plans to undertake human embryo (stem cell) experimentation.

(e) And for such other relief as to this Honorable Court may seem just and equitable.

/s/

R. Martin Palmer, Jr., #03594
21 Summit Avenue
Hagerstown, MD 21740
(301) 790-0640

Dated: August 10, 1999

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

| | | |
|---|---|---|
| MARY DOE, *et al.*, | ) | |
| | ) | |
| Plaintiffs, | ) | |
| | ) | |
| v. | ) | C.A.No.PJM-99-2428 |
| | ) | |
| DONNA SHALALA, *et al.*, | ) | |
| | ) | |
| Defendants. | ) | |
| | ) | |
| | ) | |

MOTION TO DISMISS OR,
IN THE ALTERNATIVE FOR SUMMARY JUDGMENT

Now come the defendants, by the undersigned counsel, and move pursuant to Rules 12(b)(1), 12(b)(6), and 56 for the dismissal of the complaint or, in the alternative, for the entry of judgment in their favor.

In support whereof, the defendants state:

1. There is no dispute of material fact and the defendants are entitled to judgment as a matter of law.

2. This case represents the second attempt by at least one of the named plaintiffs to challenge certain medical research. The first effort, also by a named plaintiff "Mary Doe, a preborn child in being," was rejected when iter alia, this Court held that preborn children lacked standing. Doe v. Shalala, 862

F. Supp. 1461 (D.Md. 1994)(Messitte,J.). In the present complaint, a similar attempt is made to fashion standing for "Mary Doe, a human embryo 'born' in the United States." Like the 1994 case, the present "Mary Doe" seeks to represent a class consisting of herself and "all other frozen embryos similarly," situated, "a request that this Court squarely rejected in its 1994 opinion. Doe, 862 F. Supp at 1426, complaint, at 1. Added to "Mary Doe" is a purported organization, "the National Association for the Advancement of Preborn Children," the identity of whose members is nowhere alleged in the complaint.

3. For the reasons articulated in the accompanying memorandum of law, the Court should dismiss the complaint or, in the alternative, grant summary judgment in favor of the defendants.

4. Principles of res judicata should prevent "Mary Doe" from seeking to establish standing. This court concluded that she lacked standing in 1994. Nothing has changed that should alter that conclusion. Even if one reached the merits of "Mary Doe's" standing, the analysis reaches the same result: she lacks standing as a matter of law.

5. The purported National Association for the Advancement of Preborn Children also lacks standing. It is the burden of the plaintiff to allege facts sufficient to establish the Court's jurisdiction. The instant complaint contains no facts that permit the Court to conclude that this association meets

the relavent standing tests. In the absence of any such allegations of fact in the complaint, the complaint should be dismissed or, in the alternative, summary judgment granted for the defendants.

6. Even if the plaintiff overcame the standing hurdle, on the merits there is no genuine issue of materials fact: the law provides that embryos are not "persons" under the Fourteenth Amendment entitled to the equal protection and due process.

WHEREFORE, the defendants respectfully request that the Court dismiss the complaint with prejudice or, in the alternative, enter judgment in their favor.

Respectfully submitted,
Lynne A. Battaglia
United States Attorney

By: /s/
Allen F. Loucks
Assistant United States Attorney
6625 United States Courthouse
101 West Lombard Street
Baltimore, Maryland 21201-2692
410-209-4800

CERTIFICATE OF SERVICE

I certify that on January 5, 2000, I caused a copy of the foregoing motion to dismiss, or in the alternative, for summary judgment, memorandum in support thereof, request for hearing and order to be mailed, first class, postage prepaid, to R. Martin Palmer, Esq., Library Place, 21 Summit Ave., Hagerstown Maryland 21740.

/s/

Allen F. Loucks
Assistant United States Attorney

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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| MARY DOE, *et al.*, | ) | |
| | ) | |
| Plaintiffs, | ) | |
| | ) | |
| v. | ) | C.A.No.PJM-99-2428 |
| | ) | |
| DONNA SHALALA, *et al.*, | ) | |
| | ) | |
| Defendants. | ) | |
| | ) | |

REQUEST FOR HEARING

The defendants request a hearing on their motion to dismiss or, in the alternative, for summary judgment.

/s/
Allen F. Loucks
Assistant United States Attorney

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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| MARY DOE, *et al.*, | ) | |
| | ) | |
| Plaintiffs, | ) | |
| | ) | |
| v. | ) | C.A.No.PJM-99-2428 |
| | ) | |
| DONNA, SHALALA, *et al.*, | ) | |
| | ) | |
| Defendants. | ) | |
| _____ | ) | |

ORDER

UPON CONSIDERATION of the motion to dismiss or, in the alternative, for summary judgment, the opposition thereto, the record in this case and the applicable law, it is this ____ day of ____, 2000

ORDERED that the motion to dismiss or, in the alternative, for summary judgment BE and HEREBY IS GRANTED; and it is further

ORDERED that judgment BE and HEREBY IS ENTERED in favor of the defendants as of the date of this order, and is further

ORDERED that the clerk shall mail copies of this order to counsel for the parties and close this case.

/s/
Peter J. Messite
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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| MARY DOE, *et al.*, | ) | |
| | ) | |
| Plaintiffs, | ) | |
| | ) | |
| v. | ) | C.A.No.PJM-99-2428 |
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| DONNA, SHALALA, *et al.*, | ) | |
| | ) | |
| Defendants. | ) | |
| | ) | |

MEMORANDUM IN SUPPORT OF MOTION TO DISMISS OR IN THE ALTERNATIVE FOR SUMMARY JUDGMENT

I. Introduction

Plaintiffs in this action seek to enjoin the Defendants from planning to undertake research involving human embryos, particularly stem cell research, and to declare that such embryos are "persons" under the Fourteenth Amendment to the Constitution, entitled to equal protection and due process of law. Defendants are entitled to judgment on both of the plaintiffs' claims because plaintiffs have failed to present a case or controversy that may be adjudicated by the court. First, plaintiff Mary Doe is not a "person" able to assert a claim under the Fourteenth Amendment. Roe v. Wade, 410 U.S.113,158 (1973). Second, both the individual plaintiff and the organizational plaintiff have failed to meet Article III standing

requirements or prudential standing requirements. Plaintiffs' allegations of injury are speculative and attenuated, and lack the "concrete adverseness," Baker v. Carr, 369 U.S.186, 204(1962), required to meet the "case or controversy" requirement of Article III. Moreover, organizational plaintiffs have filed this complaint to air "generalized grievances" and disagreements with the Government that are not justiciable by the court, United States v. Richardson 418 U.S. 166, 174 (1974). Because of these failings, plaintiffs' motion for waiver of appointment of a guardian ad litem for Mary Doe must also fail.

Alternatively, defendants are entitled to judgment as a matter of law on the pleadings because plaintiffs have failed to state claim upon which relief can be granted. Plaintiffs seek a ruling from the court concerning the Fourteenth Amendment that directly contravenes controlling decisions of the Supreme Court, *see, e.g.* Roe v. Wade, 410 U.S. at 158, and prior ruling by this court. Doe v. Shalala, 862 F. Supp. 1421, 1426 (D. MD. 1994) *vacated as moot on appeal,* 57 F.3d 1066 (4th Cir. 1995), and on matters that are subject to agency discretion and beyond judicial review. Apter v. Richardson, 510 F.2d 351, 355 (7th Cir. 1975); Ujvarosy v. Sullivan, 1993 W.L. 150033 (N.D. Cal. 1993); Marinoff v. HHS, 456 F. Supp. 1120, 1122 (S.D.N.Y. 1978); Grasetti v. Weinberger, 408 F. Supp. 142, 150 (N.D.Cal. 1976).

## II. Facts

### A. The National Bioethics Advisory Commission and Human Stem Cell Research

At the present time, no federal funding is being used to support research involving stem cells derived from embryos, although such research may be conducted in the private sector. In November 1998, President Clinton charged the National Bioethics Advisory Commissions ("NBAC"), a Presidential Advisory Commission appointed under the Federal Advisory Committee Act, 5 U.S.C. App. 1, with the task of conducting a thorough review of issues associated with human stem cell research, balancing all ethical and medical considerations . The stem cell is a unique and essential cell type found in animals, capable of continually reproducing themselves to renew tissue throughout an individual's life. *See* NBAC, "Ethical Issues in Human Stem Cell Research, Executive Summary" (September 1999)("NBAC Report") at 1, available at http://bioethics.gov/cgi-bin/bioeth.counter.pl. Embryonic stem cells, found in early-stage embryos, retain the ability to develop into nearly any cell type. *Id.* At this time, human stem cells can be derived from, among other sources, human fetal tissue following an elective abortion, and human embryos that are created by in vitro fertilization that are no longer needed by couples being treated for infertility. *Id.* At 2.

On July 13-14, NBAC held a public meeting in Cambridge,

Massachusetts, at which a draft Report by NBAC on human stem cell research was publicly discussed. The final NBAC report was issued September 1999. The meeting agenda, transcript of the meeting, and final NBAC Report are available at http://bioethics.gov/cgi-bin/bioeth_counterpl. The NBAC report recommended that federal funding for use and derivation of embryonic stem cells should be limited to two sources: cadaveric fetal tissue and embryos remaining after infertility treatments, and recommended that relevant statutes and regulations be amended to permit federal funding of such research. NBAC Report at 4. The NBAC Report also recommended stringent requirements for donation of fetal tissue and embryos for research,[1] recommended procedures for oversight and review of research probtocols involving stem cell research, and recommended that the private sector voluntarily adopt the rec-

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[1]Recommendation 5: Requirement for Donation to Stem Cell Research of Embryos That Would Otherwise Be Discarded After Infertility Treatment. Prospective donors of embryos remaining after infertility treatments should receive timely, relevant, and appropriate information to make informed and voluntary choices regarding disposition of the embryos. Prior to considering the potential research use of the embryos, a prospective donor should have been presented with the option of storing the embryos, donating them to another woman, or discarding them. If a prospective donor chooses to discard embryos remaining after fertility treatment, the option of donating them to research may be presented. (At any point, the prospective donors' questions - including inquires about possible research use of any embryos remaining after infertility treatment - should be answered truthfully, with all information that is relevant to the questions presented.)

During the presentation about potential research use of embryos that would other wise be discarded, the person seeking the donation should: a) disclose that the stem cell research is not intended to provide medical benefit

ommendations of the report when conducting stem cell research that is not federally-funded. NBAC Report 6-11.

B. Department of Health and Human Services Appropriations Acts and Human Subjects Protection Regulations Pertaining to Stem Cell Research

The Department of Health and Human Services ("DHHS") is prohibited by appropriations law from using any appropriated funds "for the creation of human embryo or embryos for research purposes; or research in which a human embryo or embryos are destroyed, discarded, or knowing subjected to risk of injury or death greater than that allowed for research on fetuses in utero under [DHHS human subject protection regulations] 45 C.F.R. 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C.289f(b)." P.L. 106-113, section 510. The DHHS has concluded that, because stem cells are not

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to embryo donors, b) make clear that consenting or refusing to donate embryos to research will not affect the quality of any future care provided to prospective donors, c) describe the general area of the research to be carried out with the embryos and the specific research protocol, if known, d) disclose the source of funding and expected commercial benefits of the research with the embryos, if known, e) make clear that embryos used in research will not be transferred to any woman's uterus, and f) make clear that the research will involve the destruction of the embryos.

Recommendation 6: No Promises to Embryo Donors That Stem Cells Will Be Provided to Particular Patient-Subjects. In federally-funded research involving embryos remaining after infertility treatments, researchers may not promise donors that stem cells derived from their embryos will be used to treat patient-subjects specified by the donors.

Recommendation 7: Commerce in Embryos and Cadaveric Fetal Tissue. Embryos and cadaveric fetal tissue should not be bought or sold. NBAC Report at 6-7.

embryos, this provision does not prohibit use of federal funds for research using human stem cells derived from embryos with non-federal funding. To extent that such cells are considered human fetal tissue, they are subjected to federal requirements on transplantation of fetal tissues and the prohibition on the transfer of fetal tissue for valuable considerations, sections 498A and 498B of the Public Health Service ("PHS") Act, 42 U.S.C. 289g-l through 289g-2.[2] *See* DHHS, "Draft National Institutions of Health Guidelines for Research Involving Human Pluripotent Stem Cells" (December 1999) available at http://nih.gov/news/stemcell/draftguidelines.htm. 64 Fed. Reg. 67576 (December 2, 1999).

C. The Draft National Insitutes of Health Guidelines for Research Involving Stem Cells

To ensure that research using stem cells is conducted appropriately , the Director of the National Institutes of Health ("NIH"), a component of DHHS, convened a working group of the Federal Advisory Committee to the Director to advise the

[2]Requirements for research involving transplantation of fetal tissue and restrictions on transfer of fetal tissue for valuable consideration include: a) a written signed statement providing informed consent by the donor of the tissue; b) a separate written statement by the attending physician regarding independent and separate consent by the donor concerning the abortion procedure and donation of the tissue and full disclosure of research interests, medical risks , and risks to privacy; c)a separate written consent by the researcher regarding the source of the tissue; and d) prohibitions against purchase of fetal tissue and solicitation or acceptance of fetal tissue as directed donation for use in transplantation, which carry criminal penalties. 42 U.S.C. 289g.1 through 289g-2.

Committee on guidelines and oversight for research involving stem cells. On April 8, 1999, the working group held a public meeting to discuss draft guidelines, and on December 2 the NIH issued draft Guidelines for Research Involving Human Pluripotent Stem Cells ("Draft NIH Guidelines"), seeking public comment through January 31, 2000. *Id.* The Draft NIH Guidelines apply to applications for NIH funding of research involving utilization of embryonic stem cells derived without DHHS funding and derivation or utilization of embryonic stem cells from fetal tissue. Any future research funded by NIH under the guidelines will involve only stem cells derived from either fetal tissue or from early human embryos that are the products of in vitro fertilization in excess of clinical need, that are not implanted in a woman's uterus, and have not reached the stage when the first major tissue type is formed. *Id.* at 67577. Such research may involve stem cells derived from embryos without federal funding. No research involving stem cells derived from fetal tissue or early human embryos will be funded by NIH until the Draft NIH Guidelines are issued in final form, following public comment and review.

The Draft NIH Guidelines prescribe conditions that should be met before any NIH funds are used to support any future stem cell research involving embryos, including: a)voluntary donation; b)a clear separation between the decision to create embryos for fertility treatment and the decision to

donate embryos in excess of clinical need for research purposes with different individuals serving as the attending physician and the researcher; c) use only of frozen embryos, to enable donor to have time to consider donation of embryos in excess of clinical need; do removal of identifiers; e)no restrictions on recipients of transplantation of the stem cells; f)informed consent of donors following discussions of the guidelines, research use of the stem cells, and a statement that donated embryos will not be transferred to another woman's uterus, will not survive the cell derivation process, and will be handled respectfully; g)approval of the research protocol by an Institutional Review Board, following DHHS human subjects protection regulation at 21 C.F.R. Part 56 and 45 C.F.R. Part 46; h) documentation submitted to NIH with the research application substantiating compliances with the NIH Guidelines. *Id* at 67577-78.

## III. Argument

### A. Res Judicata As Regards "Mary Doe"

On September 26, 1994, this Court held that a preborn child in being , "Mary Doe," lacked both individual and representational standing to sue to enjoin the activity of the National Institutes of Health Human Embryo Research Panel. Doe v. Shalala, 862 F. Supp. 1421 (D. Md. 1994) (Messitte,J.). The Court specifically addressed the standing of [w]ould-be Plaintiff "Mary Doe". Id. at 1423, 1426-1427. The Court rejected

the attempt to assert individual or representational standing for "a pre-born child in being as a human embryo." Id. at 1426 (internal quotes omitted). The Court rejected the effort with the following language:

> There are several reasons why the suit cannot proceed as to "Mary Doe." First philosophical and religious considerations aside, the Supreme Court has made it clear that the word "person," as used in the Fourteenth Amendment, does not include the unborn. Roe v. Wade, 410 U.S. 113, 158, 93 S. Ct. 705, 729, 35 L. Ed. 2d. 147(1973). It has thus been held that embryos are not persons with legally protectable interests with in the meaning of Fed.R.Civ.P.17(c) such that appointments of guardians ad litem are warranted or required. See Roe v. Casey, 464 F. Supp.483 (E.D.Pa.1978), affd, 623 F.2d 829 (3d Cir, 1980). The Court sees no distinction between fetuses in utero or ex utero.

Roe, 862 F. Supp. At 1426

In short, this Court has already evaluated and rejected the standing of this alleged plaintiff. The doctrine of res judicata exist to avoid the need to relitigate decided matters. Res judicata precludes the assertion of a claim after a judgment on the merits in prior suit by parties or their privies based on the same cause of action. Harnett v. Billman 800 F.2d 1308, 1312 (4thCir. 1986). The preclusive affect of a prior judgment extends beyond claims or defenses actually presented in previous litigation, for "[n]ot only does res judicata bar claim that were

raised and fully litigated, it prevents litigation of all grounds for , or defenses to, recovery that were previously available to the parties, regardless of whether they were asserted or determined in the prior proceeding." Peugeot Motors of America, Inc. v. Eastern Auto Distributors, Inc. 892 F.2d 355, 359 (4th Cir. 1989), quoting Brown v. Felsen, 442 U.S. 127, 131 (1979) (internal quotation marks deleted). Having decided that "Mary Doe" lacks standing in 1994, the Court should not need to address this issue yet again.

B. No Justiciable Case Or Controversy

1. Plaintiff Mary Doe Is Not a "Person" Capable of Sustaining This Action

Mary Doe, described as "a human embryo 'born' in the United States (and subsequently frozen in which state of cryo-reservation her life is presently suspended),"is not a "person" capable of asserting of sustaining the claim alleged in the complaint, either independently or, as discussed below, through appointment of a guardian ad litem. Under Article III, Section 2 of the Constitution, the judicial power of the United States extends to cases and controversies, which are definite and concrete disputes, "touching the legal relations of parties having adverse legal interests." Doe, 862 F. Supp. at 1427, *citing* , Aetna Life Ins. Co. v Haworth , 300 U.S. 227 (1937). "It must be a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distin-

guished from an opinion advising what the law would be upon hypothetical state of affairs." *Id.* Inherent to the case or controversy requirement is the concept that there must be "persons," parties with personal interests at stake in the proceeding. *See, e.g.,* Sierra Club v. Morton, 405 U.S. 727, 732 (1972).

As this court has already determined, " the Supreme Court has made it clear that the word 'person' as used in the Fourteenth Amendment, does not include the unborn." Doe v. Shalala 862 F. Supp. 1421, 1426, *citing* Roe v. Wade, 410 U.S. at 158. Cases cited in plaintiffs' memorandum of law[3] arguing that the standard for viability established in Roe must be flexible and accord with scientific advances, Anders v. Floyd, 440 U.S. 445 (1979), Colautti v. Franklin, U.S. 379 (1979), and Planned Parenthood of Central Missouri v. Danforth, 428 U.S. 52 (1976), do not overturn the Supreme Court's fundamental finding in Roe that the unborn are not persons under the Fourteenth Amendment. First, under Roe, viability is the point at which the State has an interest in protecting fetal life, 410 U.S. at 163. There is no suggestion in Roe that a fetus attains the status of a "person" under the Fourteenth Amendment at the point of viability. Second, Roe defines viability as the point at which "the fetus has the capability of meaningful life outside the womb, or is potentially able to live outside the mother's

[3]The memorandum was filed in connection with the plaintiffs' "motion to recuse the ordinary requirement for the appointment of guardian ad litem or, in the alternative, to appoint such a guardian."

womb, albeit with artificial aid." 410 U.S. at 160. Cases cited by plaintiffs confirm the flexible standard set in Roe. Viability is established "when, in the judgment of the attending physician on the particular facts of the case before him, reasonable likelihood of the fetus' sustained survival outside the womb, with or without artificial support." 439 U.S. at 388; 428 U.S. at 64. Viability refers to potential, rather than actual, survival of the fetus outside the womb. 440 U.S. 445. None of these cases extend the standard of viability to a situation described by plaintiffs, in which the potential fetus must be implanted into the uterus to develop to become potentially viable. Further, the scientific technology described by plaintiffs for sustaining Mary Doe "in cryo-preservation" is not novel since this court's prior conclusion that an embryo is not a person under the Fourteenth Amendment. And cases cited by plaintiffs concerning the viability standard were presumably duly considered by this court in reaching its previous conclusions that the term "person" as used in the Fourteenth Amendment does not include the unborn either in utero or ex utero. Doe, 862 F. Supp. at 1426.

2. Plaintiff Mary Doe Lacks Independent and Representational Standing

Plaintiff Mary Doe is also unable to meet Article III standing requirements sufficient to establish a case or con-

troversy that is justiciable by this court. The question of standing is the essential component of the case or controversy requirement. Valley Forge Christian College v. Americans United, 454 U.S. 464, 471 (1982), Allen v. Wright, 468 U.S. 737, 751 (1984). Whether a plaintiff has a sufficient stake in a matter to obtain judicial resolution of a dispute is the threshold question in testing for constitutional standing to sue. Sierra Club, 405 U.S. at 732. At a minimum, Article III standing requires the plaintiffs to show that they have personally suffered some actual or threatened injury as a result of the putatively illegal conduct of the defendant, that the injury fairly can be traced to the challenged action, and is likely to be redressed by a favorable decision. Bennett v. Spear, 520 U.S. 154, 162 (1997); Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992).

To show injury, a party must have a personal stake in the outcome of the controversy, to assure concrete adverseness between the parties. Baker v. Carr, 369 U.S. at 204. The injury must be distinct and palpable, not merely conjectural. Allen v. Wright, 468 U.S. at 751. The plaintiff must have legally protected interest to a concrete, particularized, actual, and imminent invasion. Defenders of Wildlife 504 U.S. at 560. An assertion of conjectural, hypothetical, or speculative harm will not suffice to establish standing. Id.; Laird v Tatum, 408 U.S. 1, 13-14 (1972). Nor will it do to allege injury to others which a

plaintiff purports to represent. U.S. Dept. of Labor v. Triplett, 494 U.S. 715, 720 (1990). In addition to injury the plaintiff must show that the injury concretely and demonstrably has resulted from defendant's singular action, Simon v. Eastern Kentucky Welfare Rights Organization, 426 U.S. 26, 45 (1976), and that it is likely (as opposed to merely speculative) that the injury will in fact be readdressed by favorable decision. Id. at 46; Defenders of Wildlife, 504 U.S. at 561. There must be a substantial likelihood that the relief sought from the court, if granted, will remedy the harm. Duke Power Company v. Carolina Environmental Study Group, Inc., 438 U.S. 59, 78 (1978).

Plaintiff Mary Doe is unable to show the type of imminent, palpable injury required for Article III standing. Plaintiffs have failed to provide any specific information regarding Mary Doe, including whether or not she meets any of the proposed requirements for stem cell research supported by federal funds set forth in the NIH Guidelines. It is not clear where Mary Doe is located, whether she was created through an in vitro-fertilizaiton process, whether she has been determined to be in excess of clinical need, whether she has been donated with full informed consent, and whether there is any particular proposed research project that involves Mary Doe. Plaintiffs have failed to show Mary Doe is imminently threatened by participating in any federally-funded research

project. In fact, no federal support is currently being provide for stem cell research, and it is not clear that Mary Doe would be a candidate for such research, even if it were funded. At best, alleged threatened harm to Mary Doe is speculative. Moreover, plaintiffs have not shown that any alleged injury concretely and demonstrably arise from defendants' actions that can be redressed by a favorable decision by the court. Even if federal funding is provided to support stem cell research, private firms will derive stem cells for that research. And a decision by the court enjoining the Government from supporting stem cell research would not prevent continued stem cell research in the private sector.

Mary Doe is also unable to assert the legal rights of "similarly-situated" embryos. A plaintiff may not ordinarily assert the legal rights of others, unless the party has sufferd an injury in fact, has a close relation to the third party, and there is some hindrance to the third party's ability to protect his or her interest. Powers v. Ohio, 499 U.S. 400, 411 (1991). As shown above Mary Doe has not shown injury in fact sufficient to support individual standing. Nor have plaintiffs shown that Mary Doe has a close relation to "similarly-situated" embryos, having failed to state with any particularity the circumstances of Mary Doe or the allegedly "similarly-situated" embryos, that she is capable of representing the interests of these third parties.

3. The Purported Association Lacks Standing

The National Association for Advancement of Preborn Children (the "Association") is also unable to meet standing requirements, either in its own right or a representative of its members, needed to establish a case or controversy that is justiciable by this court. An organization may have standing in its own right to seek judicial relief from injury to itself and to vindicate whatever rights and immunities the association itself may enjoy. Warth v. Seldin, 422 U.S. 490, 511 (1975). When determining whether an association has standing in its own right, a court must conduct the same inquiry as in the case of an individual, determining if the association has a personal stake in the matter, having suffered an actual or threatened injury that can fairly be traced to the challenged action by the defendant and that is likely to be redressed by a favorable decision by the court. Allen v. Wright, 468 U.S. at 751; Valley Forge, 454 U.S. at 472. Mere interest in a problem, no matter how-long standing or how qualified the litigant, will not satisfy the injury requirement. Sierra Club v. Morton, 405 U.S. at 739.

An organization may also have standing as the representative of its members whose association ties have been harmed. Warth, 422 U.S. at 511. An organization may have representational standing when its members would have standing to sue in their own right, when the interests the organization

seeks to protect are germane to the organization's purpose, and neither the claim, not the relief sought, requires participation of individual members in the lawsuit. United Food and Commercial Workers Union Local 751 v. Brown Group, Inc., 517 U.S. 544, 545 (1996); Hunt v. Washington State Apple advertising Comm'n, 432 U.S. 333, 343 (1997).

The Association has failed entirely to establish either organizational or representational standing. The complaint contains no information whatsoever about the Association, and fails to even assert that the association has suffered any type of actual or threatened injury that has been caused by the defendants or that can be redressed by the court. Likewise, the Association has not even stated who its members are, or asserted any facts to support a finding that those members have standing to sue in their own rights, that there are interests the organization seeks to protect that are germane to its purpose, or that the relief sought does not require participation of individual members.

Even if the Association could meet standing requirements, prudential limitations would guide the court to refuse to adjudicate the claims presented. Gladstone Realtors v. Village of Bellwood, 441 U.S. 91, 99 (1979). The Supreme Court has identified three considerations as prudential ones: 1) a plaintiffs' interest must come with in the "zone of interest" arguably protected by the status in question; 2) a plaintiff may

not air "generalized grievances" shared by all or a large scale class of citizens; and 3) a plaintiff ordinarily may not assert the legal rights of others, unless the party has suffered an injury in fact, has a close relation to the third party, and there is some hindrance to the third party's ability to protect his or her own interest. Valley Forge, 454 U.S. at 474-475, *citations omitted.* The Association has sustained no identified injury within the "zone of interest" created by the Constitution, any pertinent statute, or the Draft NIH Guidelines. The Association is, in fact, airing generalized grievances of interest to citizens as a whole and it is not able to assert the constitutional rights of others.

C. Failure To State A Claim Upon Which Relief Can Be Granted

Assuming, arguendo, that the plaintiff's overcame the standing hurdles, defendants are entitled to summary judgment because plaintiffs have failed to state a claim upon which relief can be granted. Fed. Rule of Civil Procedure 12(b)(6). Even if the facts as stated by the plaintiffs are taken as true, defendants are entitled to judgment as a matter of law. As discussed above, plaintiffs request that the court declare that embryos are "persons" under the Fourteenth Amendment to the Constitution entitled to equal protection and due process of law, which is contrary to existing Supreme Court precedent. Roe v. Wade, 410 U.S. at 158: Second, plaintiffs seek to enjoy defendants from planning to support research on stem cell

research. However, it has already established that the decision by NIH when and whether to fund research is a discretionary decision beyond judicial review. Apter v. Richardson, 510 F. 2d at 355; Ujvarosy v. Sullivan, 1993 W.L. 150033 (N.D. Cal. 1993); Marinoff v. HHS, 456 F. Supp. at 1122; Grasetti v. Weinberger, 408 F. Supp. at 150 Thus, plaintiffs are unable to present facts that would entitle them to a favorable ruling by this court.

D. Guardian Ad Litem Motion

The plaintiffs have filed a motion "to recuse" the requirement of appointment of a guardian ad litem. The Court should deny the motion as moot because the plaintiffs lack standing and because the complaint fails to state a claim upon which relief can be granted. Dismissal of the complaint should render the motion moot.

As this court has previously held, embryos, whether in utero or ex utero, are not persons under the Fourteenth Amendment with legally protectable interests within the meaning of Federal Rule of Civil Procedure 17(c), and thus appointment of a guardian ad litem is neither warranted or required. Doe v. Shalala, 862 F. Supp. at 1426, *citing*, Roe v. Casey, 464 F. Supp. 483 (E.D. Pa. 1978), *aff'd* 623. F.2d 829 (3rd Cir. 1980). The court's ruling in Doe was based on the Supreme Court's ruling in Roe v. Wade that the word "person" as used in the Fourteenth Amendment does not include the unborn. 410

U.S. at 158. The Roe Court recognized that the unborn may be represented by guardians ad litem under tort law or inheritance or other devolution, as argued by the Plaintiffs, but determined that the interests represented by those appointments are either those of the parents, or contingent upon live birth. 410 U.S. at 161-62. Further, viability is the point at which the State's interest in protecting the unborn is triggered. 410 U.S. at 163. In arguing that guardians ad litem may be appointed to protect the Fourteenth Amendment interests of the unborn, plaintiffs fail to cite any cases that overturn the Roe precedent concerning application of the term "person" under the Fourth Amendment, or merit a reversal of this court's previous ruling that appointment of a guardian ad litem is neither warranted nor required to represent alleged interests of the unborn under the Fourteenth amendment. Thus the court should deny plaintiff's motion to recuse the ordinary requirement for appointment of a guardian, or to alternatively appoint a guardian ad litem in this case.

## IV. Conclusion

The Court should grant the motion to dismiss or, in the alternative, for summary judgment.

Respectfully submitted,
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

| | | |
|---|---|---|
| MARY DOE, *et al.*, | ) | |
| | ) | |
| Plaintiffs, | ) | |
| | ) | |
| v. | ) | C.A.No.PJM-99-2428 |
| | ) | |
| TOMMY G. THOMPSON, *et al.*, | ) | |
| | ) | |
| Defendants. | ) | |

DEFENDANTS' MOTION TO DENY
PLAINTIFFS' MOTION FOR CONTEMPT AND CLOSE CASE

Now come the defendants, by the undersigned counsel, and move for the denial of the Motion for Contempt filed by Plaintiffs and the closure of the instant cause of action. In support whereof, the defendants state:

1. Counsel for plaintiffs, R. Martin Palmer, complains that during the past year while his appeal to the Fourth Circuit and Petition to Writ of Certiorari to the Supreme Court were pending, the defendants did not file a sixty day status report as the Court originally required under the terms of the administrative closure of the case. During all this time plaintiff's counsel did not protest that the status reports were not filed.

2. As the court will recall, the reason for the administrative closure was the anticipation that a change in administration as a result of the 2000 presidential election might change

the policy fashioned by the previous administration under the "National Institutes of Health Guidelines for Research Involving Human Pluripotent Stem Cells." That is precisely what happened. After much consideration, on August 9, 2001, President Bush announced a new policy on stem cell research.

3. The reports were required in order to apprise the Court if there was a change in the policy. Once the policy changed and the case was appealed there was nothing for this Court to decide. Now that the case is back before this Court, counsel wishes to resume as though nothing has happened in the previous year. Counsel cannot have it both ways.

4. Federal courts must always be mindful of their obligation to avoid rendering advisory opinions. See Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 240-41, (1937). While it may not necessarily be appropriate to wait until an injury actually materializes, there must be a sufficiently concrete controversy to justify the court taking jurisdiction. See Arch Mineral Corp. v. Babbitt, 104 F.3d 660, 665 (4th Cir. 1997). In determining whether a claim is ripe for adjudication, two factors must be considered: (1) the extent to which the claim is fit for adjudication; and (2) the hardship to the parties. See Abbot Labs v. Gardner, 387 U.S. 136, 149, (1967), overruled on other grounds, Califano v. Sanders, 430 U.S. 99, 105 (1977).

5. To determine whether a claim is fit for adjudication the Court must examine whether the question presented is a

"purely legal one and not whether the agency rule or action giving rise to the controversy is final and to dependent upon future uncertainties or intervening agency rulings." Charter Fed. Sav. Bank v. Office of Thrift Supervision, 976 F.2d 203, 208 (4th Cir. 1992).

6. As the new policy on stem cell research develops it is clear that the factual basis of this original suite has been undermined. The defendants' letter of October 16, 2002 to the Court indicated that the current facts and policy on stem cell research have mooted the original suit brought by the plaintiffs. Plaintiffs' counsel does not and cannot contradict this assertion. Therefore, the Court should close this case.

WHEREFORE, the defendants respectfully request that the Court deny the motion for contempt and close the case as moot.

Respectfully submitted,

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IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 03-2254

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MARY DOE, a human embryo "born" in the United States (and subsequently frozen in which states of cryo-preservation her life is presently suspended) individually and on behalf of all other frozen human embryos similarly situated; THE NATIONAL ASSOCIATION FOR THE ADVANCEMENT OF PREBORN CHILDREN,

Plaintiffs-Appellants,

v.

TOMMY G. THOMPSON, in his official capacity as Secretary of Health and Human Services; U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; HAROLD VARMUS, in his official capacity as Director of the National Institutes of Health; NATIONAL INSTITUTES OF HEALTH,

Defendants-Appellees.

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ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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# BRIEF FOR APPELLEES

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## STATEMENT OF SUBJECT MATTER AND APPELLATE JURISDICTION

1. **Subject Matter Jurisdiction.** Plaintiffs invoked the district court's jurisdiction under 28 U.S.C. § 1331. Appendix ("App.") at A12 (Complaint, ¶2).

2. **Appellate Jurisdiction**. Plaintiffs seek review of a final judgment of the district court dismissing this case for lack of an ongoing case or controversy. App. A50, A60. This Court has jurisdiction under 28 U.S.C. § 1291.

3. **Timeliness Of The Notice Of Appeal**. The district court's order was filed on July 3, 2003. App. A50. A timely motion for reconsideration was denied on August 5, 2003. App. A60. Plaintiffs filed a notice of appeal on October 3, 2003. App. A61. The notice is timely under Fed. R. App. P. 4 (a)(1).

## STATEMENT OF THE ISSUE PRESENTED FOR REVIEW

Whether the district court properly dismissed on mootness grounds this suit challenging the Clinton Administration's policies regarding federal funding of human stem cell research.

## STATEMENT OF THE CASE

This civil action, brought near the end of the Clinton Administration, sought to challenge then-existing policies regarding federal funding of human stem cell research. In early 2001, shortly after President Bush assumed office, the district court issued an interlocutory order administratively closing the

case pending the new Administration's ongoing review of the underlying issues. Plaintiffs filed an appeal from that order, but this court dismissed the appeal for lack of appellate jurisdication. See Doe v. Shalala, No. 01-1298 (Feb 7, 2002).

On remand from this Court, the district court has now issued a final order dismissing the case as moot. As the court explained, the Clinton Administration policies, which were the subject of this suit, have been withdrawn and superseded by a new and different policy of the Bush Administration. App A50-54. Thus, this case no longer presents a live controversy. See id.

## STATEMENT OF FACTS

### A. Background: Stem Cells And The July 1999 Draft Report Of the National Bioethics Advisory Commission

This case arises against the backdrop of the Clinton Administration's efforts to develop policies regarding federal funding of human embryonic stem cell research. Embryonic stem cells, which come from the inner cell mass of a human embryo, have the potential to develop into all or nearly all of the tissues of the human body.

In November 1998, President Clinton charged the National Bioethics Advisory Commission (an entity whose charter has since expired) with the task of reviewing the ethical and medical issues associated with human stem cell research. In July 1999, the Commission issued a draft report.

The draft report recommended that federal funding be made available for such research, subject to a number of specified conditions and limitations. See App. A32.

### B. Plaintiffs' Lawsuit, the Clinton Administration Guidleines, And Plaintiffs' First Appeal

1. This lawsuit was filed in August 1999. Plaintiffs are Mary Doe, "a human embryo 'born' (produced or brought into life) in the United States" (App A12 (Complaint, ¶4)), and the National Association for the Advancement of Preborn Children (NAAPC). The NAAPC "is an organization dedicated to advocacy for the equal humanity and personhood of preborn children, including 'children in vitro.'" (App. A12 (Complaint, ¶ 5)).

Plaintiffs' complaint alleged that "the President's Advisory Commission and the National Institutes of Health violate Mary Doe's rights under the Fourteenth Amendment to the United States Constitution by issuing and/or implementing recommendations for human embryo experimentation" (App. A11-A12 (Complaint, ¶1)). The complaint sought "an injunction ordering the current administration, the Department of Health and Human Services and the National Institutes of Health to cease and desist any and all plans to undertake human embryo (stem cell) experimentation" (App. A12 (Complaint, ¶1)).

The government responded to plaintiffs' complaint by filing a motion to dismiss or in the alternative for summary judgment. App. A26. The motion explained at the outset that

"[a]t the present time, no federal funding is being used to support research involving stem cells derived from embryos" (App A32 (Memorandum In Support of Motion To Dismiss Or In The Alternative For Summary Judgment, at p.2)).

The motion noted that in September 1999, subsequent to the filing of plaintiffs' complaint, the National Bioethics Advisory Commission had issued its final report regarding the issues associated with human stem cell research. The final report recommended, among other things, that research involving the derivation and use of human embryonic stem cells from embryos remaining after infertility treatments should be eligible for federal funding. App A33[1].

The motion also noted that following the final report of the National Bioethics Advisory Commission, the National Institutes of Health (NIH, a component of the U.S. Department of Health and Human Services, had published for notice and comment draft guidelines regarding stem cell research funding. 64 Fed. Reg. 67576 (Dec 2, 1999). The motion reiterated that "[n]o research involving stem cells derived from * * * human embryos will be funded by NIH until the Draft NIH Guidelines

[1]As explained in a White House fact sheet, "[e]mbryonic stem cells are derived from excess embryos created in the course of infertility treatment. As a result of standard in vitro fertilization practices, many excess human embryos are created. Participants in IVF treatment must ultimately decide the disposition of these excess embryos, and many individuals hav donated their excess embryos for research purposes." Fact Sheet, Embryonic Stem Cell Research, August 9, 2001, available online at http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html .

are issued in final form, following public comment and review." App. A36.

Against this backdrop, the motion urged that plaintiffs' complaint be dismissed and/or that summary judgment be granted for the government. The motion argued in particular that plaintiffs' complaint presented not justiciable case or controversy, that plaintiffs lacked standing to sue, and that, in any event, the government was entitled on the merits to judgment on the pleadings. App. A26-A46.

2. The district court made no ruling on the government's motion. On August 25, 2000, NIH issued its guidelines for federally funded research involving human stem cells. 65 Fed. Reg. 51976. Subject to further implementation requirements, the guidelines would have permitted federal funding for human embryonic stem cell research in limited circumstances where the embryos in question were created for the purposes of fertility treatment and were in excess of the clinic need of the individuals seeking such treatment, and where there were also sufficient assurances of informed consent on the part of the individuals seeking such treatment, and where there were also sufficient assurances of informed consent on the part of the individuals who had sought fertility treatment and wished to donate excess embryos. See id.

Soon after assuming office, however, President Bush indicated that the NIH guidelines promulgated by the previous

Administration might not be implemented and that the issue of stem cell research would be the subject of reexamination and further study.

Against this backdrop, the district judge (Hon. Peter J. Messitte) stated at a hearing in this case that it would be inappropriate for the court to consider the merits of policies promulgated by the Clinton Adminstration when it was clear that the new Administration was in the process of revisiting the question. Accordingly, on February 26, 2001, the district court issued an interlocutory order "administratively closing" the case. See Order (Feb. 26, 2001). The order stated that "[f]or the reasons set forth at this afternoon's hearing, the Clerk is directed to ADMINISTRATIVELY CLOSE this case. Defense counsel shall advise Plaintiff's counsel and the Court every sixty days hereafter regarding the status of the Human Pluripotent Stem Cell Research Guidelines." Id. Plaintiffs subsequently filed a notice of appeal (4th Cir. No. 01-1298) from the trial court's "hold" order.

### C. President Bush's Statement Of August 9, 2001 And The Subsequent Withdrawal Of The Clinton Administration Guidelines

On August 9, 2001, while plaintiffs' first appeal was pending, President Bush issued a statement addressing the question of human stem cell research. The President stated that "[m]y administration must decide whether to allow federal

funds, your tax dollars, to be used for scientific research on stem cells derived from human embryos." See Remarks By The President On Stem Cell Research, August 9, 2001, available online at http://www.Whitehouse.gov/news/releases/2001/08/20010809-2.html. As the President explained, "[a] large number of these embryos already exist. They are the product of a process called in vitro fertilization, which helps so may couples conceive children. When doctors match sperm and egg to create life outside the womb, they usually produce more embryos than are implanted in the mother. Once a couple successfully has children, or if they are unsuccessful, the additional embryos remain frozen in laboratories." Id.

The President emphasized that "[b]ased on preliminary work that has been privately funded, scientists believe further research using stem cells offers great promise that could help improve the lives of those who suffer from many terrible diseases – from juvenile diabetes to Alzheimer's, from Parkinson's to spinal cord injures. And while scientists admit they are not yet certain, they believe stem cells derived from embryos have unique potential." Id.

The President continued that "[a]s a result of private research, more than 60 genetically diverse stem cell lines already exist. They were created from embryos that have already been destroyed, and they have the ability to regenerate

themselves indefinitely, creating ongoing opportunities for research. I have concluded that we should allow federal funds to be used for research on these existing stem cell lines, where the life and death decision has already been made." Id.[2]

The President made clear that while federal funds would become available for research involving existing stem cell lines, only research meeting specified criteria would be eligible for support. Those criteria are: (1) the stem cells must have been derived form an embryo that was created for reproductive purposes; (2) the embryo was no longer needed for these purposes; (3) informed consent must have been obtained for the donation of the embryo; and (4) no financial inducements were provided for donation of the embryo. Having determined that federally funded research in this area should be permitted subject to these conditions, the President added that "I will also name a President's council to monitor stem cell research, to recommend appropriate guidelines and regulations, and to consider all of the medical and ethical ramifications of bio-medical innovation." Id.

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[2]The term "stem cell lines" is defined as follows: "to create embryonic stem cells for research, a 'stem-cell line' must be created from the inner cell mass of a week-old embryo. If they are cultured properly, embryonic stem cells can grow and divide indefinitely. A stem cell line is a mass of cells descended from the original, sharing its genetic characteristics. Batches of cells can then be separated from the cell line and distributed to researchers." See Fact Sheet, Embryonic Stem Cell Research, August 9, 2001, supra.

NIH is currently implementing the President's policy. In November 2001, NIH formally announced the withdrawal of those sections of the August 25, 2000, guidelines previously promulgated by the Clinton Administration that pertain to embryonic stem cell research. 66 Fed. Reg. 57107 (Nov. 14, 2001). NIH also created a "Human Embryonic Stem Cell Registry" listing human embryonic stem cells that meet the applicable eligibility criteria. NIH is now funding scientists "to conduct research on existing human embryonic stem cells and to explore the enormous promise of these unique cells, including their potential to produce breakthrough therapies and cures." App. A52-53 n.2 (citing http://stemcells.nih.gov/fedPolicy/NIHfedPolicy.asp).

### D. This Court's Dismissal of Plaintiffs' First Appeal And The District Court's Dismissal Of This Case As Moot

As noted, plaintiffs in February 2001 had filed a notice of appeal from the district court's order placing the case on "hold" pending the Bush Administration's revisiting of the issue of the government's policies regarding federally funded stem cell research. On February 7, 2002, this Court issued an unpublished ruling "dismiss[ing] the appeal for lack of jurisdiction because the order is not appealable." Doe v. Shalala, No. 01-1298, Order (February 7, 2002), at 2. This Court explained that "[t]he order here appealed is neither a final order nor an

appealable interlocutory or collateral order. It merely removes the case from the district court's live docket until the issue of federal funding for stem cell research is settled by the Bush Adminsitration." Id. at 3.

On remand from this Court's dismissal of the appeal, both sides filed further submissions in the district court regarding the appropriate course of proceedings. The government urged, among other things, that the case should now be dismissed on mootness grounds because the Clinton Administration policies that were the subject of the suit had been withdrawn and had been superseded by the new and different policy of the Bush Administration. App A47-A49.

The district court agreed and entered a final order dismissing the case as moot in July 2003. App A50. In an accompanying opinion, the court explained that the revised policy of the Bush Administration has "mooted the original suit brought by Plaintiffs." App. A53. On that basis, the court entered a final judgment for the government. App. A50.

## SUMMARY OF ARGUMENT

As the district court properly concluded, this case presents no ongoing controversy. This suit was brought during the Clinton Administration to challenge guidelines issued during that Administration. The premise of the complaint was that human embryos were at risk of destruction because of the

alleged possibility of stem cell extraction by federally funded researchers. Whatever validity that premise may have had at the time, it is now untenable. Under the new policy announced by President Bush in August 2001 and currently being implemented, federal funds will be made available for human embryonic stem cell research only with respect to preexisting stem cell lines, i.e. lines originating from stem cells with respect to which the extraction process was initiated prior to the President's August 2001 address. Thus, an embryo with respect to which the process of stem cell extraction was not undertaken prior to that time, faces no subsequent risk of such extraction supported by federal funds. Accordingly, the threatened harm that formed the basis for this lawsuit no longer exists.

## STANDARD OF REVIEW

Whether the case presents an ongoing case or controversy is a legal issue considered by this Court de novo.

## ARGUMENT
## THE DISTRICT COURT PROPERLY DISMISSED THIS SUIT FOR LACK OF A LIFE CONTROVERSY

**A.** Article III confers jurisdiction only where a case or controversy exists. U.S. Const., Art. III. The "case-or-controversy requirement subsists through all stages of federal judicial proceedings." Lewis v. Continental Bank Corp., 494

U.S. 472, 477 (1990). Thus, to sustain Article III jurisdiction, "it is not enough that a dispute [may have been] alive when suit was filed." Id. Rather, "[t]o qualify as a case fit for federal adjudication, 'an actual controversy must be extant at all stages of review.'" Arizonans for Official English v. Arizona, 520 U.S. 43, 67 (1997) (quoting Preiser v. Newkirk, 422 U.S. 395, 401 (1975)). See also Honig v. Doe, 484 U.S. 305, 317 (1988); Koger v. United States, 755 F.2d 1094, 1096 (4th Cir. 1985) ("actual controversy must exist at all stages").

The premise of the complaint in this case was that human embryos were at risk of destruction by federally funded researchers. See, e.g., App A23 (Complaint, ¶54). Whatever validity that premise may have had when the lawsuit was filed, it is now untenable.

Plaintiff's complaint challenged the position of the Clinton Administration regarding human embryonic stem cell research. See App. A11-A25 (Complaint). The portion of the NIH guidelines promulgated by the Clinton Administration that pertain to embryonic stem cell research were never implemented and were formally withdrawn in November 2001. See 66 Fed. Reg. 57107. The policy announced by President Bush on August 9, 2001 established that federal funds are to be made available for human embryonic stem cell research only with respect to preexisting stem cell lines, i.e., lines originating from stem cells with respect to which the derivation process

was initiated prior to the President's announcement. See pp. 7-9, supra. Pursuant to that policy, which is currently being implemented by NIH, an embryo with respect to which the process of stem cell extraction was not undertaken prior to the time of the President's address on August 9, 2001, faces no subsequent risk of such extraction supported by federal funds.

Simply stated, this lawsuit has been overtaken by events. Under the revised policy currently under implementation, the threatened harm that formed the basis for plaintiffs' complaint does not exist. Accordingly, the case is now moot.

**B.1.** Plaintiffs seek to premise an ongoing live controversy on the wholly speculative "possibility that the Bush Administration [might] change its policy regarding stem cell research at some point in the future." Appellants' Br. 13. Alternatively, plaintiffs offer the "possibility that the Democratic nominee for the 2004 Presidential Election will be elected and that new, Democratic administration will assume office in 2005, an administration that may well be more sympathetic to and revive the policies of the Clinton Administration regarding federal funding of stem cell research." Appellants' Br. 14.

On the basis of such speculation, plaintiffs seek to invoke the principle that a defendant's "mere voluntary cessation of illegal conduct" does not automatically moot an ongoing challenge to that conduct. See United States v. W.T. Grant Co.,

345 U.S. 629, 632 (1953); see also, e.g., Adarand Constructors, Inc. v. Slater, 528 U.S. 216, 222, (2000); American Legion Post 7 v. city of Durham, 239 F.3d 601, 605-06 (4th Cir. 2001). The rationale for the "voluntary cessation" principle is that defendants in a pending suit should not be able to evade judicial review by temporarily halting their illegal conduct only to restart it once the suit is dismissed as moot. As the courts have admonished, mootness precepts should not be subject to manipulation leaving the defendant "free to return to his old ways." See W.T. Grant Co., 345 U.S. at 632; Lyons Partnership, L.P. v. Morris Construction, Inc., 243 F.3d 789, 800 (4th Cir. 2001); see also, e.g., City News & Novelty, Inc. v. City of Waukesha, 531 U.S. 278, 284 n.1 (2000) (voluntary cessation concept "traces to the principle that a party should not be able to evade judicial review, or to defeat a judgment, by temporarily altering questionable behavior").

That principle has no application when a new President sets aside the policies of his predecessor and establishes his own, very different policies. Under plaintiffs' theory, abandoned policies of past administrators would regularly be subject to judicial challenge based on the possibility that some future administration might reinstate the rejected policy. But as this Court has made clear, an ongoing action challenging a legislative or administrative policy becomes moot when the policy in question is repealed. See American Legion Post 7 v. City of

Durham, 239 F.3d 601 (4th Cir. 2001) (challenge to repealed provisions of zoning ordinance moot). Indeed, that is the case even when a statute is amended after being held unconstitutional by a district court. See Valero Terrestrial Corp v. Paige, 211 F.3d 112 (4th Cir. 2000) (constitutional challenge mooted when legislature amended challenged provisions). As this Court emphasized, "statutory changes that discontinue a challenged practice are 'usually enough to render a case moot, even if the legislature possesses the power to reenact the statute after the lawsuit is dismissed.'" Id. at 116 (quoting Native Village of Noatak v. Blatchford, 38 F.3d 1505 (9th Cir, 1994)).

In both of the above-cited cases, this Court distinguished City of Mesquite v. Aladdin's Castle, Inc., 455 U.S. 283 (1982), where the Supreme Court considered the merits of a municipal licensing ordinance even though the ordinance had by that point been repealed. In so ruling, the Supreme Court stressed that "[i]n this case the city's repeal of the objectionable language would not preclude it from reenacting precisely the same provision if the District Court's judgment were vacated," id. At 289, and that "[i]ndeed, the city had announced just such an intention." Id. At 289 n.11. As this Court explained in Valero Terrestrial Corp., "Mesquite is generally limited to the circumstance, and like circumstances, in which a defendant openly announces its intention to reenact 'precisely the same

provision' held unconstitutional below." Valero Terrestrial Corp., 211 F.3d at 116 (quoting City of Mesquite, 455 U.S. at 289 & n.11). See also City of Durham, 239 F.3d at 605 (City of Mesquite "is distinguishable because in that case, the city had repeatedly amended the ordinance at issue in response to court rulings and had announced its intention to re-enact the challenged provision if the judgment in question was vacated on mootness grounds").

As in Valero Terrestrial Corp. and City of Durham, there is no basis whatsoever for speculation that the government would reinstitute old policies if the litigation here is dismissed as moot. Plaintiffs ask for an advisory opinion based on the merest speculation that some administration, at some point, might institute a version of the policy that has now been formally set aside. Article III makes clear that they are not entitled to such a ruling.

2. Plaintiff's suggestion that the case is "capable of repetition, yet evading review," suffers from the same defect. See Appellants' Br. 15. The prospect of "repetition" is wholly speculative. Moreover, there is no reason whatsoever to conclude that if some future administration were to institute a new policy, it would be of such short duration as to escape review. Plaintiff's challenge here did not become moot because such policies are inherently unchallengeable while they are in place. It became moot because the policy in question was never

implemented and was later formally withdrawn.[3]

In short, it was the new Administration's decision to reassess the policies at issue, rather than any inherently short duration of such policies, that caused this case to become moot. And as demonstrated, the general rule is that an ongoing action challenging a legislative or administrative policy becomes moot when the policy in question is repealed. That rule is directly applicable here, and compels affirmance of the district court. See, e.g., Pressley Ridge Schools v. Shimer, 134 F.3d 1218, 1221 (4th Cir. 1998) (dismissing case as moot, and rejecting "capable of repetition, yet evading review" argument, where challenged provision had been repealed and amended").

3. Finally plaintiffs suggest that the case is not moot because "[b]y allowing federal funding of stem cell research using the limited supply of stem cells extracted from human embryos prior to 9:00 p.m. on August 9, 2001, the Government has threatened [to] deplete the available supply of human embryo stem cells, thereby making it more likely that additional human embryos, like Mary Doe, will have to be

[3]The sequence of events underlying this litigation is illustrative. The draft National Bioethics Advisory Commission report that prompted this lawsuit was issued in July 1999. See p.3., supra. Plaintiffs filed their compliant in August 1999. The final National Bioethics Advisory Commission report was then released in September 1999. Next, draft guidelines were promulgated in December 1999. Ultimately, NIH guidelines were published in August 2000. At no point during this timeline was any federal funding available for human embryonic stem cell research; even the final NIH guidelines issued in August 2000 remained subject to further implementation requirements. See pp. 3-7, supra.

destroyed in order to extract enough stem cells for privately funded and other non-federally funded research." Appellants' Br. 17. This last suggestion is equally unavailing.

This litigation concerns only the question of federally funded research. As stressed, the critical limitation of existing policy is that federal funding is to be made available only with respect to stem cell lines derived from stem cells with respect to which the extraction process was undertaken prior to the President's announcement in August 2001. What actions non-federally funded researchers may or may not take against this backdrop is, in the present context, sheer speculation, and touches upon matters wholly beyond the scope of this suit.[4]

[4]Because, for the reasons stated, the case clearly presents a no ongoing Article III case or controversy, there is no need or reason to address whether plaintiff Mary Doe might otherwise have standing to sue or whether plaintiff National Association for the Advancement of Preborn Children (NAAPC) would satisfy the prerequisites for organizational standing.

## CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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APRIL 2004

## CERTIFICATION OF SERVICE

I hereby certify that on this 19th day of April, 2004, I served the foregoing **"BRIEF FOR APPELLEES"** upon the United States Court of Appeals for the Fourth Circuit by overnight courier (FEDEX), and upon counsel by causing two copies to be sent by overnight courier (FEDEX) to:

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